S. HRG. 103–511

HUMAN SUBJECTS RESEARCH: RADIATION EXPERIMENTATION

HEARING

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

DETERMINING THE MAGNITUDE OF THE RADIATION RESEARCH, TO DETERMINE WHERE THESE EXPERIMENTS TOOK PLACE, TO DETERMINE WHAT RECORDS EXIST, TO DETERMINE HOW GREAT THE DANGERS WERE, TO DETERMINE IF PARTICIPANTS WERE INFORMED OF THE RISKS AND BENEFITS OF THE RADIATION EXPERIMENTS AND TO DETERMINE HOW MUCH HARM WAS DONE.

JANUARY 13, 1994 (WALTHAM, MA.)

Printed for the use of the Committee on Labor and Human Resources

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CONTENTS

STATEMENTS

THURSDAY, JANUARY 13, 1994

HUMAN SUBJECTS RESEARCH: RADIATION EXPERIMENTATION

THURSDAY, JANUARY 13, 1994

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Waltham, MA.

The Committee met, pursuant to notice, at 10:30 a.m., in the Howe Hall, Fernald School, 200 Trapelo Road, Waltham, MA, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Senator Kennedy.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. Good morning. We might come to order if we could, please.

We want to welcome all of you. And first of all, we want to thank Mr. O'Meara who is the superintendent here for all of his courtesies in making available the opportunity for us to be here today, for Congressman Markey and myself.

I might just say before we get started, I understand we had a fire drill here. That always happens when Ed Markey has a hearing. I can't help with just opening the hearing on a lighter note. One of my very favorite recollections was of President Kennedy when he was in Naval Intelligence before going out to the Pacific in World War II. And he told the story of when he went to a factory in South Carolina, and he was talking to the factory members about the dangers of espionage and sabotage and that if the workers saw a fire in the factory, they ought to determine the origin of the fire before they determine how to extinguish it. And if the fire was made from wood, put water on it. If it was oil and gas, put CO2 on it. Electricity, put foam on it. But never put water on an oil and gas fire because it just spreads and you have disastrous results.

And after he gave this kind of briefing he asked whether there were any questions. A man stood from the back of the room and said, "Now, Mr. Kennedy, how are we going to know by looking from the back of the hall whether that fire is made from wood, oil or gas or electricity to know what to put on it and what not to put on it so that it wouldn't spread." So he said, "That's a very good question. There will be someone here next week to talk on that very subject." [Laughter].

So I'm sure that isn't going to be the case with our hearings here today, but I thank all of you for being with us and to stay with us and I apologize for the inconvenience. And before making a very

brief opening comment, I'd recognize our Commissioner Campbell for what words he has to say.

STATEMENT OF PHILIP CAMPBELL, COMMISSIONER, COMMONWEALTH OF MASSACHUSETTS DEPARTMENT OF MENTAL RETARDATION

Commissioner CAMPBELL. Thank you, Senator. On behalf of the Department of Mental Retardation, the Fernald State School, I just wanted to welcome both the Senator and the Congressman and to emphasize the importance of the subject before this Committee today.

The recently appointed Task Force and this Committee will continue to look into a rather bleak period of time, over 40 years ago, in the care and services to people with mental retardation. I think it is important that we take the time to review what might have happened those decades ago. Because although safeguards, greater safeguards are in place today, it is only through remaining vigilance will we continue to minimize the chances that people with mental retardation will be exploited.

And I thank both the Congressman and the Senator for their leadership in this area and look forward to full acknowledgment of what may have happened decades ago and in turn see what steps could be taken in the future to minimize any exploitation of the vulnerable population of people with mental retardation.

So on behalf of the Department, I again want to thank you for your leadership and welcome you back to Massachusetts at the Fernald.

The CHAIRMAN. Well, thank you very much, Commissioner. We have, as you mentioned, I know Ed Markey and I have had a number of opportunities to be out here at Fernald School over a long period of time. We have had special interest in the issues of the mental retardation and the workings of the Fernald School. And so we welcome very much the chance to be here and I think speaking just personally, once again underlines the importance of the issues which are before us here today, that particularly affect some of the most vulnerable in our society.

Last month, the Nation was shocked to learn that at the years after World War II the Federal government sponsored radiation experiments on human subjects without their consent. A government-wide and nation-wide effort is now under way to uncover the nature and extent of such experiments, the harm that was done, the remedies that should be made available to those who were the victims of those experiments, and the steps needed to assure that this kind of irresponsible and degrading research never takes place again.

It is already clear that a number of these experiments took place in Massachusetts, including some here at the Fernald School where our Senate Committee is meeting today.

I am pleased that Ed Markey is joining us, because he has played a leading role in recent years in the efforts to bring the experimentation to light. Often he has been a lonely eloquent voice in uncovering this shameful chapter in our medical history.

In 1986, as Chairman of the House Subcommittee on Energy Conservation and Power, Congressman Markey released a land-

mark report entitled "American Nuclear Guinea Pigs: Three Decades of Radiation Experiments on U.S. Citizens." That report revealed the frequent, systematic use of human subjects in radiation research, including 31 experiments in which 695 persons were exposed to radiation that provided little or no medical benefit to the subjects.

Congressman Markey's report was stonewalled by the Administration then in power. But today there is a different leadership and a different attitude, and I commend Secretary of Energy Hazel O'Leary and the Clinton Administration for their commitment to do the right thing, to tell the Nation what happened, and to make amends to those whose lives and health were endangered.

And in rectifying this situation, Congress intends to work closely with the Administration. Our hearing this morning is the beginning of a lengthy oversight and legislative process to deal effectively and responsibly with this issue.

We intend to get answers. We want to know what was done in Massachusetts and in every other State where these experiments were conducted. We want to know what records exist, how great the dangers were, how much consent, if any, was obtained for the research, and how much harm was done. Once we have this information, we can enact legislation to help the victims and prevent any repetition of these abominable practices.

We will now receive a statement for the record by Representative Joseph P. Kennedy II.

[The prepared statement of Mr. Joseph P. Kennedy II follows:]

PREPARED STATEMENT OF JOSEPH P. KENNEDY II

I would like to thank Senator Kennedy for convening this important hearing of the Senate Labor and Human Resources Committee. I would also like to recognize Rep. Edward Markey for being at the forefront of investigating human radiation tests at a time when the former Reagan and Bush administrations turned a deaf ear. Each of today's witnesses will play a critical role in a thorough examination of human radiation experiments, and I thank each of you for participating in today's hearing.

Today's hearing at the Fernald School causes us to revisit a chilling chapter in our Nation's history—an era where human radiation experiments were conducted on often unwitting subjects in the name of the Cold War. This setting challenges us not only to remember but to respond. Some say that even the most egregious cases, those involving human guinea pigs, were conducted for the "greater good." But it is questionable whose best interests were at stake in every case, particularly when subjects may not have been properly informed and when many were among society's most vulnerable. Many already determined to have been participants in government-sponsored radiation tests were among those who frequently turn to our government for care. By preying upon an essentially captive audience of subjects ranging from the infirm and the elderly to those on active duty military and others seeking care at veterans hospitals, medical ethics standards are put to the test.

It is time for our government to acknowledge this dark legacy and make amends. We can accept no less than a comprehensive investigation and a full, impartial disclosure demanded of a free society. Now, our government will be put to the test. Every phase of its investigation will be subject to the close scrutiny and the watchful eye of a skeptical American public who has learned the hard lessons of decades of Cold War secrecy.

President Clinton and Energy Secretary O'Leary, in particular, are to be commended for their quick actions to respond to these troubling accounts. Already, Secretary O'Leary and other cabinet-level officials have begun to take significant steps toward restoring openness and public accountability. While finding and assembling the lost puzzle pieces of history will not be easy, it is now imperative that we move forward expeditiously with appropriate medical follow-up and compensation considerations.

The Cold War itself may now be a part of our Nation's past, but its legacy of radiation experimentation cannot be put behind us and must never be forgotten. Our government agencies and Congress cannot and will not rest until we have the answers to the many questions that have gone unanswered for so long.

The CHAIRMAN. Our witnesses today will include two subjects of the experiments conducted here at Fernald School in Massachusetts. We will also here from representatives of the Federal Agencies, private institutions involved in these and many other experiments that were carried out. Finally, we will hear from medical and ethical experts about precautions and safeguards needed in order to prevent any further abuses.

And I want to welcome all of our witness and we look forward to their testimony. And I recognize Congressman Markey.

STATEMENT OF HON. EDWARD J. MARKEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS

Mr. MARKEY. Thank you, Senator Kennedy, very much, and thank you for holding this hearing and for investigating the disturbing revelations that have come out concerning human experimentation and the Fernald School. These experiments shock and sadden me and lead me to question just how much we know about the extent and the kind of human experimentation that took place in this country from 1944 up through the 1970s. In fact, a primary reason why those experiments stopped in the 1970s is because of the leadership of Senator Kennedy, who held landmark hearings on biomedical research in the early 1970s. As a result of those hearings, Senator Kennedy sponsored legislation to protect human subjects of biomedical research. And I commend his early pioneering leadership on this important issue.

The recent acknowledgment by Federal officials that the government conducted human radiation experiments has grabbed the attention of all Americans. And the reason is that most people assumed that our country would not engage in that kind of activity. I think the fact that the Federal government, our government, funded or engaged in this kind of activity is the most disturbing aspect of this entire story. Most Americans thought that our country would not do that kind of thing.

I was particularly shocked by the Fernald School experiments because I had conducted an investigation of human radiation experiments back in 1986 and at the time was not told about these experiments. Yet clearly these experiments fit within the scope of the documents that I requested from the Reagan Department of Energy. Therefore, one question I have here today is whether the experiments described in the 1986 report constitutes the iceberg, and the more recent Fernald revelations are just the tip, or whether the report is the tip, and we have yet to find the iceberg.

The Subcommittee report that I released in 1986, American Nuclear Guinea Pigs: Three Decades of Radiation experiments on U.S. Citizens, was a staff report of the House Subcommittee on Energy. This report revealed the frequent systematic use of human subjects as guinea pigs for radiation experiments. The report provided details on 31 cases in which a total of nearly 700 persons were exposed to ionizing radiation in experiments which provided little or no medical benefit to the subjects.

The report described current Federal regulations on the use of human subjects for experiments and noted four general principles for such experiments.

One, the risk to subject should be minimized. Two, risk to subject should be reasonable in relation to anticipated benefit and the importance of the knowledge that may reasonably be expected to result. Three, subjects should be selected in an equitable manner. And four, informed consent shall be sought from each prospective subject or authorized representative. Informed consent includes a clear description of the risk and the benefits of the experimental procedure.

The experiments where children at the Fernald School were fed or injected with radioactive material violated at least two of these principles. The children at the school were members of society that deserved protection, not exploitation as experimental subjects. And their parents were deceived about the nature of the experiments when they gave their consent for participation. I use the word "deceived" advisedly. With at least one experiment, the letter from the school requesting consent never mentioned that radioactive material would be fed, noted that experimental subjects were selected from a group of our brighter students, and implied that the experiment might result in gains in weight and other improvements, particularly in the blood.

In that regard, I commend the recent statement of Dr. Charles Vest, President of MIT, who acknowledged that while doses at the Fernald School may have been relatively low, he was sorry for the experiments because of the children selected and the lack of informed consent. MIT explained that President Vest issued his statement because, quote, it seemed the decent thing to do, and I applaud his decency.

My experience in looking at human experimentation by the government, unfortunately, is that as more information becomes available, the recognized number of people exposed expands. I hope this experience will not be repeated as the Department of Energy conducts its investigation into all experiments with human subjects, but I fear that past human radiation experimentation may prove much wider than we found in 1986.

One conclusion of the report was that these experiments should never be repeated again. The report noted that radiation experiments of this type concluded in the early 1970s, and there was no evidence of such experiments that continues to this date. That is due largely, I might repeat, because of the efforts of Senator Kennedy and the legislation and the hearings which he conducted in the 1970s.

I had assumed that experiments of such nature would apply to the arrogance of the early Atomic age and the paranoia of the Cold War. But I am dismayed to find that individual scientists feel compelled even today to defend these experiments of long ago. For example, some are justifying the experiments at the Fernald School on the grounds that doses to children were low. But such defenses seem blind to other considerations of medical ethics. Subjects were selected from among the most defenseless members of the population, and the parents of these children were deceived about the nature of the experiments when they granted their consent for par-

ticipation. One cannot defend experiments that were conducted in the past that violate the standards of human decency.

I want to, again, make clear that those that run the Fernald School today are as appalled as any in our society. I want to compliment President Clinton, Secretary O'Leary, Secretary Brown, for their breathtaking candor in the way in which they are dealing with this issue. Instead of denying the existence, stonewalling access, they are opening up all Federal records. I think that is the decent and courageous thing to do. It is the least that we owe to those families that may have had the health of their loved ones affected by these experiments.

I once again want to compliment Senator Kennedy for all of his early pioneering work on this subject and hope that this hearing today can help to contribute to a further explanation and lead ultimately to the compensation which those families that have been affected deserve. Thank you.

The CHAIRMAN. Thank you very much, Congressman Markey, for all the good work you have done and continue to do.

Our first panel will lead off with two of the participants in the Fernald radiation experiments. Mr. Charles Dyer was placed in Fernald School by his mother at age 7 and discharged from the school in 1961. Currently married with two children, both his daughters have had problems. One daughter was born with internal organs reversed. His second daughter had problems with her lungs early in her life, and lost a third child. Mr. Dyer is a truck driver for a produce company, has been on workers' compensation this past year and a half due to an accident. He is unable to see a medical doctor due to a lack of health insurance. He is concerned about lumps all over his body since he was young.

Mr. Austin LaRocque is a former resident of Fernald School, member of the science club. Currently married, three healthy children. Employed as a building maintenance person. Enjoys good health.

Dr. Bertran Brill, is a Research Director and Professor of Nuclear Medicine, University of Massachusetts Medical Center.

And Dr. Belton Burrows is Chief of the Department of Nuclear Medicine at the Boston VA, is present and in the service when a number of these studies were going on and continues to serve in the Veterans' Administration to discuss the effects of radiation on humans.

Now, I just want to open up with Mr. Dyer and Mr. LaRocque. Thank you very much for coming. It is always difficult to talk about health care needs. I think all of us consider that to be a matter of enormous privacy and we want to thank you very much for being willing to come here this morning and to share with us your experience here at the Fernald School during the time that these tests were being undertaken and you were participants in them.

And I want to also indicate to others that were perhaps members of the science club or others that were involved in this program, that we would certainly value any of their comments as well as part of our total record. So any of the individuals that read about it, hear about our hearing, learn about it at sometime afterwards, if they would write to me in care of the U.S. Senate, I will make sure that their whole statements or comments are made a part of

our whole record as well and keep the record open. I have not had the chance to interview or review with all of those, and obviously, that is going to take place as part of the follow-up. But we would certainly welcome any of the others who may want to have their comments or statements or experiences part of this record, we will certainly include it.

So we thank both of you for coming and we hope you just sort of relax here this morning, to the extent that you can, and I think know that what you say is enormously helpful to all of us for trying to be of help, not only to yourselves but also to other families as well. And probably the best way we can thank you is to make sure the job gets done. And I think you can certainly have a reassurance of Ed Markey and certainly myself. We will be relentless in pursuing that justice is done in these cases. So we thank you very much for joining with us.

Maybe we will start with Mr. Dyer. Do you want to, just in your own words, tell us a little bit about your own kind of experience? Get the mike up close to you, and we look forward to hear from you.

STATEMENTS BY CHARLES DYER, FORMER RESIDENT OF FERNALD SCHOOL; MEMBER OF THE SCIENCE CLUB; AUSTIN LAROCQUE, FORMER RESIDENT OF FERNALD SCHOOL, MEMBER OF THE SCIENCE CLUB; BERTRAN BRILL, M.D., RESEARCH DIRECTOR AND PROFESSOR OF NUCLEAR MEDICINE, UNIVERSITY OF MASSACHUSETTS MEDICAL CENTER; AND BELTON BURROWS, M.D., CHIEF OF THE DEPARTMENT OF NUCLEAR MEDICINE, BOSTON VETERANS ADMINISTRATION

Mr. DYER. I appreciate what you are doing for us now. It was about time that something was being done about it instead of us hiding everything.

I never knew what was going on because at the time when this first came out, my sister brought it up to me and said, "Did you see this article in the paper?" And I said, "No," because I don't read the newspapers. And she said it was about the Fernald School here, and about the science club they had up there. And I said, Gee, I remember something there, because they gave us a Mickey Mouse watch at the MIT. And I didn't know it was a Mickey Mouse. I couldn't remember the face on it what they gave me. But I knew it was a watch and everything.

But I appreciate now that something is being done about it because I don't want to find out later that it had something to do with my children, because that's about all I can think right now to say about it.

The CHAIRMAN. This is an enormously important point, and that is because of not just the individuals that were affected by this, but it is the others, the innocents. In this instance Mr. Dyer points out the children, his family. They are, obviously, the most innocent. But I imagine you will hear during the course of the hearing there were others as well. Some of the administrators of these experiments were involved, others involved in working with the tests, didn't know about this as well.

We will hear from Mr. LaRocque, Austin LaRocque.

Mr. LAROCQUE. My name is Austin LaRocque, first of all.

We were injected through the program of the science club. Some of us were volunteers in our own way. It is very difficult to talk about this situation at this time, only because, you know, we really aren't up on the facts of these programs or know that much about the stuff that they are talking about. You people are probably a little more advanced with this than we are. But we want to stand up for our rights and we don't want it to happen to any other children in the future.

As far as I'm concerned, the school itself should not be affected by this. Because these kids that are here today are getting, I'm sure, 100 percent better treatment than we did. I don't have anything else to say at this time. Feel free to ask me a question, I will answer it to the best of my ability. Thank you.

The CHAIRMAN. Now, as I understand, you were members of the science club, and members of the science club participated in the radiation experiments?

Do you remember being told anything? You were pretty young at the time, 7 years old, in Mr. Dyer's case. Do you ever remember anybody talking to you about—any of your parents or relatives about this? Or do you just remember going in and being part of some kind of, you know, an experiment? What do you remember back there?

Mr. DYER. Well, I don't remember much about my parents because they took me up there and that was it. And I remember once she came up to see me. I think it was almost the time I was getting out. She wanted me to live with her. I told her no. So they kept me here for another year and a half. Because I felt that she wasn't my parent or nothing. So I feel that the State figured they took me over from there. I didn't know from there what was going on. My sister signed me out.

The CHAIRMAN. But you were taking milk at this time?

Mr. DYER. Yes.

The CHAIRMAN. Do you ever remember anybody telling you, when were drinking that milk, anything at all?

Mr. DYER. No they just said—we would eat separate stuff and drink separate stuff in our water, where they had us in the building on the first floor, that we were eating different foods than the other kids in the building.

The CHAIRMAN. Did you know why you were eating different foods?

Mr. DYER. No, I didn't.

The CHAIRMAN. Did anybody ever explain why you were going to eat different foods?

Mr. DYER. No. They just said it was vitamins and stuff.

The CHAIRMAN. Do you remember, Mr. LaRocque? Did you know you were eating different foods?

Mr. LAROCQUE. Yes, we were eating different foods than most of the other children. But there was no explanation for it, other than the fact that we belonged to the science club, and we had to assume that this was part of their program and that's all I can tell you.

The CHAIRMAN. Did you feel the food was better or was worse?

Mr. LAROCQUE. Well, in relation to the food at the Fernald School, or for any institution, for that matter, it all tastes basically about the same. [Laughter] I'm trying to keep a sense of humor about this situation. It's not easy, believe me.

The CHAIRMAN. Well, I will leave that one alone, I guess.

Let me ask you, you know, medically now, how do you feel now? Do you have real concerns about your current medical conditions or conditions of your children as a result of the radiation experiments?

Mr. LAROCQUE. I have a—if I'm entitled to speak.

The CHAIRMAN. Go ahead, please.

Mr. LAROCQUE. I have a smaller feeling of medical problems. I have a son and a daughter that have had medical problems in their stomach, digestive system, which I have the same. I have gone for GI series, upper and lower. At that time the doctor could not find anything because he wasn't looking for the subjects that were involved. He was looking for normal ulcer or whatever else may occur. So there was no real results. So I'm not going to say that this is part of it or not. This will be up to the doctor. I believe this would be up to a doctor to decide. I'm not a doctor so, you know, I will let it in their hands.

The CHAIRMAN. But you'd like to know, wouldn't you?

Mr. LAROCQUE. By all means.

The CHAIRMAN. You'd like your children to know.

Mr. LAROCQUE. I am definitely concerned for my children. My children and I have discussed it, which we have never talked about me being here. My children now are just starting to find this out.

The CHAIRMAN. Well, there is every reason to be proud, I mean, for all you have done in your life, what you have done in raising those children. The fact that you are testifying here to help a lot of other people, I would think those kids would be proud of you. I certainly am.

Let me ask you this: I imagine this weighs on you, doesn't it? Every day that you know that you have been involved in this whole experiment and you are worried now about what it's impact has been on you and your children.

Mr. LAROCQUE. At this time I would say yes.

The CHAIRMAN. And you'd like to get some medical, at least, help and assistance to let you know what the best in terms of medical science can tell you about what its impact has been on you, if any, or what it has been on your children, if any? Is that what you are——

Mr. LAROCQUE. Yes, by all means.

The CHAIRMAN. Mr. Dyer, is that the same?

Mr. DYER. Yes, I'm concerned, too, about my stomach where I have since when I first got out of this school here that I started to develop lumps on my arms, my stomach, and I had very bad ear infection when I was up here at the time. And they never took care of it. And I had to go to Mass. General Hospital, Mass. Eye and Ear when I got out of here, and they had to cut me open and put a tube in here. And even today I don't have the proper hearing or anything.

The CHAIRMAN. But you think that you are entitled, as I certainly do, to find out whether this had—the fact that you were part

of this whole kind of experiment, what the impact of that experiment has been on you and your children?

Mr. DYER. Yes.

The CHAIRMAN. And you are worried about that?

Mr. DYER. Yes.

The CHAIRMAN. Because those are questions that are not answered and not responded to.

Mr. DYER. Right.

The CHAIRMAN. And that is the very least, would you not agree with me, that we can do?

Mr. DYER. Yes.

The CHAIRMAN. And I imagine the quicker we can get around that, that that is going to ease a certain amount of anxiety.

Mr. DYER. Right.

The CHAIRMAN. Do you remember, Mr. LaRocque, any blood or urine tests associated with the special foods.

Mr. LAROCQUE. Yes, we had urine tests. We had what they call a feces test at that time. I guess it was sent in to the laboratory, whatever that place was, MIT, for analysis at that point.

We also had our urine tested. We had weight taken frequently to see if there was any change in our weight and all that garbage.

Mr. DYER. They took blood from us, too, for tests and they used to give me and a lot of time even today now I hate needles. I won't take needles because I'm allergic to them now.

The CHAIRMAN. Just before going on, as Ed Markey and I have commented on, about the amount of information that was given to you, we have as the Congressman pointed out, changed the whole process in terms of various government-sponsored research, we are going to get back to. Hopefully, there is complete compliance with that, the informed consent information.

But as I understand, at that time, I have the form which, as I understand, has been dated November 2nd, 1949. And this is the form that was used, at least to the best of the information of the personnel here, that was referenced earlier. And it says, The Mass. Institute of Technology and this institution—this is signed by the superintendent—are very much interested in various aspects of nutrition, particularly how the body absorbs various cereals, irons and vitamins. Considering the selection of a group of our brighter patients, including the name to be filled in, to receive a special diet rich in the above-mentioned substances for a period of time. We wish to keep an accurate record of the effects of these substances, such as gains in weight, other improvements, particularly in the blood. It will be necessary to make some blood tests at stated intervals similar to those which our patients are already accustomed, and which will cause no discomfort or change in their physical condition, other than possible improvement. Massachusetts Institute of Technology plans to reward patients taking part. Enclosed please find a blank which I request that you sign and return in the enclosed self-addressed stamped envelope as soon as possible. The signed and witness blank will signify that you have no objection to your son participating in this project as outlined above. You may rest assured that I personally feel this project will be of great importance, and that much valuable information concerning nutrition

can be obtained which eventually will be considerable benefit to mankind. I hope that I can count on your cooperation.

Now, do you think that, given what you know at the present time, adequately reflects the kinds of risks that evidently you were taking, being involved in this program?

Mr. DYER. That was being used?

The CHAIRMAN. Yeah, that you didn't really get much information from that statement, did you?

Mr. DYER. No.

The CHAIRMAN. How about you, Mr. LaRocque? Do you think you got much information from that statement?

Mr. LAROCQUE. Actually, I picked up nothing from it, actually, other than the fact that you are asking somebody to do something without telling them what they are doing.

The CHAIRMAN. Congressman Markey?

Mr. MARKEY. Let me just say, first of all, I think it is very brave of the two of you to come forward and talk about that period of time. We can appreciate why many others don't want to speak about it at all. So we very much appreciate your courage in coming here today.

Did anyone in the science club ever tell you about these experiments at that time?

Mr. DYER. No.

Mr. MARKEY. You didn't know that you were being experimented upon?

Mr. DYER. No.

Mr. LAROCQUE. Well, technically, you knew that they were running minor checks on you. Your blood tests and stuff like that. So I am sure that some of us felt that they were running just physical tests. Nothing to do with drugs or any of that sort.

Mr. MARKEY. So you knew, though, that you were in a special program?

Mr. LAROCQUE. Yes.

Mr. DYER. Yes.

Mr. LAROCQUE. I did.

Mr. MARKEY. The letter that was sent to your parents for signature, or approval, did you know that your parents had signed——

Mr. LAROCQUE. No.

Mr. MARKEY. [continuing]. A special consent form to put you into this program?

Mr. LAROCQUE. Well, if my parents signed, I'd like to know who they are.

Mr. MARKEY. And you, Mr. Dyer?

Mr. DYER. I'd like to know, because I never knew my mother much.

Mr. MARKEY. Were you told that it was a program that would deal with iron and vitamins and various cereals and that you were put into a special program to benefit you? What can you remember about the time?

Mr. DYER. The only thing I can remember was like they said with the cereal, it was just to check out to see if vitamins would work and make people more healthier and stuff like that. That's about all I remember on that.

Mr. MARKEY. So you were not told that it was a radioactive iron?

Mr. DYER. No.

Mr. MARKEY. Radioactive calcium that was being put in your cereal?

Mr. DYER. No, we were never told anything.

Mr. MARKEY. Mr. LaRocque?

Mr. LAROCQUE. No knowledge of that at all, whatsoever. And the first I even heard of this particular problem is just recently in the paper. And if it wasn't brought to my attention, I would have probably to this day still not have known. And I really appreciate you people coming forward for us.

Mr. MARKEY. And after the program was completed, did anyone ever follow up with you again to find out what the effects on you may have been?

Mr. DYER. No.

Mr. MARKEY. Was there any medical examination or questions asked of both of you?

Mr. DYER. No.

Mr. LAROCQUE. Not since I left the school, anyways. If they had made any physical exams, it would probably be on the record. I'm sure the school must have kept the record when they checked us. But there was no contact at the school as far as a science program or any other program from the day I left here.

Mr. MARKEY. So you heard the letter that Senator Kennedy read.

Mr. LAROCQUE. Yes.

Mr. MARKEY. Which really makes it sound like quite an attractive program to have your child put into, wouldn't you think?

Mr. DYER. Yeah. They said it would benefit us by taking vitamins and stuff. I remember that. A lot of us did say, sure, we will come, if it was a chance for us to get off the grounds. But they took us places here and there. And then they said they were going to have a Christmas party for us. And we were young kids. They took advantage of us. We were youngsters. We figured, well, we got a chance to get off the grounds for a while, get out and see something, we'll do anything.

Mr. MARKEY. So each of your parents or guardians was asked to sign a letter of consent after they received the request from the superintendent at that time to give them permission, and when we look back, people say, well, there was informed consent.

Mr. DYER. I wasn't informed.

Mr. MARKEY. That is that people were informed of what the danger was for the children, what the experiment was?

Now, that you look back, do you think that anyone was truly informed?

Mr. DYER. No.

Mr. MARKEY. To give their consent? Even if your parents or your guardians did sign these forms?

Mr. DYER. No.

Mr. LAROCQUE. Not to my knowledge.

Mr. MARKEY. That's why I use the word "deceived" in terms of this informed consent of the' 40s and the' 50s. It may have been a letter that was sent, a form may have been signed, but many did not understand or appreciate what the danger was that they were being placed in as a result of that form being signed.

Mr. LAROCQUE. I don't even know if we had—some of us had to sign our own forms. I don't remember that. But I do remember a form of some sort. But at that particular time, I could not read and write. I had no knowledge of anything, other than the fact that I do what I'm told when I'm told.

Mr. MARKEY. So my opinion is that the consent forms of that day suffer from the sin of omission and are very deceptive. In fact, in many ways, false in terms of the information which was given to the parents.

Mr. LAROCQUE. Yes.

Mr. MARKEY. And I think that it is important that everyone know that. And again, I thank you for your courage in coming forward here today.

The CHAIRMAN. Dr. Belton Burrows.

Dr. BURROWS. I would like to thank you for this opportunity to discuss my involvement in the use of radionuclides at the Framingham Cushing VA Hospital. There is one small correction I make as I go through this statement. That facility was one of 14 in 1950. That facility was one of 14 around the country which were designated radioisotope units. One function of these units was to train professional staff and other personnel in radiation surveys, and the evaluation of possible radiation exposures following industrial accidents for military action. The same facilities could be used for diagnostic studies, therapy, and medically-related research to establish procedures using radionuclides.

Members were not subject, were not the subject for studies of radiation effects. They received tracer doses of radioiodine, I meant to say, for thyroid disorders and other radionuclides for evaluation of their immunological and metabolic problems. Therapeutic doses of radioiodine were given for hyperthyroidism and thyroid cancer.

The tracers given to the subjects were small amounts of radioactive material, lower than the background radiation that everyone receives from the environment, because of natural radioactivity in the atmosphere in the earth's crust.

Consistent with State of the art medical research procedures during this time period, there was no formal process to document the patient's knowledge of, and consent for studies. There was the established practice to verbally explain what was being done and why.

From a preliminary review, it appears we have records of all the studies, or at least a lot of the studies, performed at Cushing and subsequently by the same personnel at the Boston VA Medical Center, which are contained in approximately 150 ledgers, loose-leaf notebooks, and other clinical files from 1949. These include organ scans, when the technique was introduced, obtained after 1963.

The CHAIRMAN. Dr. Brill?

Dr. BRILL. I've been involved with nucleotides and radiation medicine since the late 1950s and have participated both in the conduct of studies such as we are talking about from the Fernald School, as well as radiation effects, that is, trying to understand the effects of radiation on people, atomic bomb survivor studies and follow-up studies of patients given radioactive materials for their diagnosis and therapy and the like.

I don't think there is any question but that the informed consent that was used in the days that we are talking about now was grossly inadequate and has been rectified in more recent years so that now any proposal to the Federal Government that originates from any university has to include an informed consent statement that properly reflects the current understanding of all the risks that are associated with whatever a person is being involved with.

The studies at the Fernald School, as near as I can tell, were conducted by the world's experts at the time. And the way in which the radiation studies were done are not very much different from the ways in which subsequently the understanding of nutritional requirements has been bolstered by this type of technique.

In fact, the pioneering studies here developed the whole body counters so that one can do the kind of studies that one is now talking about by counting what's in the person, rather than counting what comes out of the urine and the stool, which is much more difficult, and enables one to do these kinds of studies at much lower doses to the subject. And indeed, as long as 5 years—as recently as 5 years ago I'm aware of studies that were proposed and certainly reviewed by the appropriate bodies from which people were concerned about how the absorption of nutrients, vitamins and minerals, put into cereals that were either french-fried or cooked in various other ways to determine bioavailability and how the intake of and absorption would be modified by the way in which cereals in particular were being processed.

So that I have some sympathy for the nature of the question that people were asking in those earlier days, and I think we are all appalled by the lack of information that people were given. Right now what you do is when you do studies on people, you give them an idea of what the radiation risks are associated with particular procedures.

And I think now the appropriate thing to do is to inform the people who have been involved in studies, that they were not fully informed about, to let them know what the doses were associated with these procedures. And if as we know today the risks of those exposures are as small as we believe them to be, based upon all the information we've selected, I think that they may be reassured about the radiation risks and still be serious victims of a time and a way in dealing with people that no longer is currently acceptable.

The CHAIRMAN. Well, let me, if I could, go back to Dr. Burrows.

In your statement, you say there was no formal process to document patient's knowledge of and consent to the studies. It was established practice to verbally explain what was being done and why.

The fact is we have no real idea what was told to these individuals, what was explained to them, what their reaction is, do we?

You don't know what was explained to any of the individuals by any of those that were involved in the process, in the experimentation, what was explained to any of those individuals, what their reactions were? Do you have any idea? Do you have any documentation that can tell that? Do you know, or do you know, personal, knowledge?

Dr. BURROWS. Well, what I said it was or is, it was the established practice. Excuse me, that I said it was the established prac-

tice and still is the practice in dealing with patients to inform them. I am in constant contact.

The CHAIRMAN. Well, there is a written informed consent now?

Dr. BURROWS. That's right.

The CHAIRMAN. That's different. So the inform consent now is a writing which outlines in detail which they can take and read the studies. Now, that gives the risk benefit ratio or tells what can be benefited and what the risks are.

Now, are you suggesting that that kind of information was available to them under your testimony as established to verbally explain what is done and why?

Dr. BURROWS. Well——

The CHAIRMAN. Do you know for each and every one of the people that are involved in those kinds of experiments, that they were given that kind of information in terms of what the potential benefits were and what the potential risks are?

Dr. BURROWS. Well, I was trying to include it under the general rubric of what happens now professionally in all of the patients that we treat or give tracer doses to.

That patients, whether they ask questions or not, we explain to them what is being done and why it is being done. And I don't know specifically in regard to every individual test that was performed back then, how completely that information transferred.

The CHAIRMAN. You don't know from any test, do you? You don't know from any test what they were told and what their reaction was?

Dr. BURROWS. Well, I'm simply saying that I was taking part in those procedures and I do not, as best as I can tell, have any different approach to the problem now than I had then.

It wasn't the first—it wasn't just because these procedures involved radioactivity that we were going through these explanations. That's true of every procedure that we used to do, diagnostically, and the evasive procedure, certainly requires that approach. And that's what I was referring to, the established practice.

Now, let me just dilate a little bit on the informed consent procedure. It requires a process, an established routine that is set up with a previously approved form that's offered the patient, and has been approved by some committee or administrative body, and which is made part of the patient's record. That structured approach would be required to have any legitimate informed consent.

Now, the other thing that we might find in searching these records, which we haven't had an opportunity yet, that might be known, a record what was being given to the patients. The person might have been informed, as well as the patients. But most often they were, if there was any, if their participation was required. But as I say, that structure did not exist until, I don't know, the mid' 60's or maybe some others will remember just when they had it, this practice was established in a formal way so that it and the documentation would be available. No, there is no written documentation.

The CHAIRMAN. Well, you have a great deal more faith in the information being made available, because the public Health Service didn't do it during the syphilis study for a period of 30 years. They never notified poor blacks that there was a cure for syphilis.

The women in the institutions in Tennessee were never told about the dangers and what the impact was going to do. They were never notified. And the CIA agents that took hallucinogenic drugs administered to them by the CIA which resulted in one of them jumping out of the window, he was never told about it.

And, you know, I think it's much better to suggest that we just didn't do the job on that. And all of us know. All of us use 20/20 hindsight in this. I wish I could be willing to accept that, given particularly what the comments have been, it was established practice to verbally explain what was being done and why. I think we are at a different period.

Can you tell me now, can you assure us that the current VA, informed consent protocols today appropriately describe the risk in any research study?

Dr. BURROWS. Well, first of all, I agree with you completely about the studies you elucidated. These were not of that nature, I can assure you of that. Most of this was straight diagnostic work.

But I'm also completely convinced that we have a very tight, well thought out and organized program with human studies, subcommittees, and the research committees, and the need for going through quite a lengthy process to be sure that any work that's done was the purpose of using it in a research report.

The CHAIRMAN. Well, you are giving us the assurance today that there are no research involving human subjects that are not conforming to the requirements in terms of the informed consent, ethical guidelines?

Dr. BURROWS. Yes, that's correct.

The CHAIRMAN. There is none that are going on today?

Dr. BURROWS. I'm sure of that, within my own experience, at least.

The CHAIRMAN. To your knowledge?

Dr. BURROWS. Yes.

The CHAIRMAN. Let me ask you this: Have there been any others that have not been—that have been taking place either in Massachusetts or to your knowledge outside of Massachusetts?

Dr. BURROWS. None that I know of.

The CHAIRMAN. Wait a minute.

Dr. BURROWS. Excuse me.

The CHAIRMAN. Outside of these examples that we have had today, and that currently have been made available in terms of the news in the press? Have there been any others that we are not familiar with?

Dr. BURROWS. Well, not that I personally am aware of. I've read most of the reports that I had access to. I don't have—I haven't had a chance to review everything.

The CHAIRMAN. Well, you would know certainly now in terms of what, in the VA, this is an area of responsibility that you have and have had over a long time. You would know, wouldn't you, if there is any research that is being done in terms of human subjects with veterans?

Dr. BURROWS. Well, my own responsibility is confined with the Boston VA Medical Center.

The CHAIRMAN. Well, can you tell us with regard to Boston, that responsibility? Can you give us those assurances?

Dr. BURROWS. Well, indeed I can.

The CHAIRMAN. You can.

Dr. BURROWS. Now, I'd like to refer you also to this morning's New York Times, which has an op. ed. article, the background for which I happen to do research just a month or so ago, for different purposes. And I found it just a coincidence that it would appear on my doorstep this morning. And I refer to those who haven't read it that it really gets to the nub of this issue of human experimentation, which we have not had any contact with.

The CHAIRMAN. Now, I'd ask Dr. Brill, can you give us the assurances that, to your knowledge here, you are an expert on these issues, not only here, but internationally, I know you do work on the impact on the Chernobyl children and others. Can you give us assurances that there has not been other experimentation, human experimentation, since the time of the issue of the protocols in terms of informed consent that has gone on without the enforcement of the informed consent protocols?

Dr. BRILL. Gee, I'm not sure how to respond to that because, you know, informed consent——

The CHAIRMAN. Well, you can answer yes or no.

Dr. BRILL. To the best of my knowledge, yes.

The CHAIRMAN. There has been?

Dr. BRILL. There has been nothing that we don't know about now that would create concern for human experimentation.

The CHAIRMAN. Well, concern. Tell me what others have been going on that might be going on that may not concern you but may concern some others.

Dr. BRILL. Well, you know, the truth of the matter is that when things go through and seek Federal funding, they go through a very fine screen.

The CHAIRMAN. I'm not asking about that. I'm asking you whether you know of any.

Dr. BRILL. I know of none.

The CHAIRMAN. Of going on, any research on human subjects that are taking place in Massachusetts today that are not complying with the informed consent?

Dr. BRILL. No, sir.

The CHAIRMAN. Do you know any that have been going on in the outside of those which have been generally published in terms of both Massachusetts, the Fernald School, the other hospitals in Boston and the VA?

Dr. BRILL. No. I would like to say one thing. It seems to me that there needs to be a distinction between government-sponsored work and university hypothesis testing work. All of the studies that I did for many, many years, 24 years I had support by the Atomic Energy Commission or its derivative agencies or the Public Health Service, but during all of that time, these were ideas that were proposed by physicians and scientists working with us who have questions they were trying to learn the answers to.

I have never had, and I don't think—I don't know anybody who is worked in the university community who has been asked by the university to do something by the CIA or the Department of Defense or the Atomic Energy Commission that they themselves didn't have a reason for pursuing.

The CHAIRMAN. Well, let's get back to this, then.

Do you know of any universities in Massachusetts that are conducting experimentations on human subjects?

Dr. BRILL. No, I don't.

The CHAIRMAN. That are not conforming to the informed consent?

Dr. BRILL. No, I don't.

The CHAIRMAN. Well, I don't think that they should be.

Dr. BRILL. No, they shouldn't be, and I don't think they are.

The CHAIRMAN. I appreciate the answer.

Let me just give a very quick reaction. You know, I wrote down a couple of the comments, the studies at this time are not greatly different. You are talking about at the earlier period of time when the Fernald School was going on, not greatly different than many of the studies that are going on. You have some sympathy. You are appalled at the lack of information that was given to them.

I mean, aren't you appalled at the lack of the fact that the most vulnerable people in our society, which were young people, 7, 8 years old, that are in an institution, aren't you appalled that they were the ones selected? Aren't you appalled that there was not follow up in terms of medical kind of caring in terms of treatment and notification, even after we have gone through all of these kinds of changed atmosphere, in terms of informed consent, that someone might have said, well, we ought to, even in retrospect, let some of these individuals know that what has happened to them? I mean, aren't you—I mean, maybe I am wrong, but just listening to you sort of talk about this, I mean, I would think that there are a lot of things to be appalled by. I mean, in terms of the circumstances which were raised about this, looking back at it then and looking forward to where we are now.

Dr. BRILL. I was talking about the magnitude of the radiation exposures that people received at that time are not different in great——

The CHAIRMAN. Did you know that then? That's the issue. Who knew it then?

Dr. BRILL. Well, at that time.

The CHAIRMAN. And can you define for us what a safe exposure of radiation is?

Dr. BRILL. I can say that we have never detected late effects from radiation in the kinds of doses that we are talking about in the calcium 47 or the calcium and iron follow ups. However, the reason that it was done, as near as I can tell, from talking to the people who were involved, was that the children were on high cereal intakes, and Quaker Oats, if that was the company, was interested in seeing——

The CHAIRMAN. Why weren't we testing MIT students? Were they on high cereal intakes? [Applause]

Dr. BRILL. I think the reason was that at that point in time there were no—what we now have is clinical research centers where people are maintained in the hospital in circumstances in which intake and output can be monitored. It's almost impossible on an ambulatory population, students at MIT, to get them to take a——

The CHAIRMAN. What about some of our excellent private schools around here? Why not do it on those?

Dr. BRILL. I think they probably should have done it. If they did it anyplace, they shouldn't have focused on a population that was captive and had no alternative. So I don't disagree.

All I was talking about was the way in which, medically, the exposures were conducted, the amount of the dose then, is maybe two or three times higher that now with better instrumentation we are able to perform. That was the only point I was making.

The CHAIRMAN. Congressman Markey? Thank you.

Mr. MARKEY. Dr. Brill, you heard Senator Kennedy read the letter, the consent form that the parents, guardians of the science club students here at the Fernald back in the' 40s perhaps signed. Do you think that was a consent form that gave enough information to the parents, to the guardians that they would know what would be happening to their children?

Dr. BRILL. Not at all. It would be completely unsatisfactory in terms of the policies and procedures that have been well accepted for the last 20-some-odd years.

Mr. MARKEY. Did the scientists in the 1940s know that, that it was inadequate? Your opinion now hearing what this letter was and knowing what they knew about radiation at that time, do you think that they meant to be deceptive at that time?

Dr. BRILL. I doubt it. I don't think so. I think that the people who were doing these studies were highly ethical people who were chasing scientific information that they thought might benefit people, and perhaps even these particular children in terms of modifying their diet, so that as to overcome inadequacies in the dietary requirements that they were receiving.

Mr. MARKEY. Well, let me ask you the question another way. Do you think that these scientists really believed that the parents of the children in the science club would have given permission for radioactive iron and calcium to be fed to their children if they had used those words? In other words, if the parents had heard the word "radioactive" materials, rather than iron and calcium, do you think they would have given permission at that time without asking many more questions about the effects upon their children?

Dr. BRILL. I think in the early 1940s and early' 50s, there was so much excitement about the peaceful avenue and everything that was going to be derived from the use of these twinkling things, that you could have easily told people at that time what you knew about radioactive materials and they would have accepted entry into the study, and depending upon how the warmth and the friendliness and the openness of the interaction, I think that people would have accepted.

Mr. MARKEY. I disagree with you 100 percent.

I think after the bombs were dropped on Hiroshima and Nagasaki, if the parents here in 1946,' 47,' 48,' 49,' 50, heard the word "radioactive" related to their children, told that they were going to be put in a special program to be fed radioactive iron and calcium, that there would have been great difficulty in obtaining the kind of consent form signatures that obviously were obtained by this institution at that time.

Dr. BRILL. You may well be right. And I think clearly the informed consent was inadequate.

Mr. MARKEY. Let us go back again to this period, because I think this does touch upon what the real problem for the cold war period was.

Mr. Dyer and Mr. LaRocque and all of the other children at that time were really, in a lot of ways, unwittingly drafted as foot soldiers into the cold war era battles against communism so that more can be found out about radioactivity. And they were kept from knowing about it, they or their families, because of the interests in keeping a lot of this secret. They kept it secret even from the subjects themselves.

Let's look at the letter. The letter says, it will be necessary to take some blood tests at stated intervals, similar to those to which our patients are already accustomed and which will cause no discomfort or change in their physical condition other than possibly improvement.

Now, let's go back to the 1940s about the State of knowledge about radioactive calcium, radioactive iron. Do you think that it is appropriate for scientists at that time to guaranty that there would be, at worse, improvements in the child's condition being fed radioactive iron and calcium at that time? Or do you think that the science at that time was still uncertain that there was substantial debate within the community? It might have been a minority position in the scientific community, but nonetheless debate transpiring as to what the real effects were, and in fact that is why the experiments were being conducted in order to find out what those consequences were, which may not have been benign or shown improvement, but in fact wound out up adverse for those who were being experimented.

Dr. BRILL. I would disagree entirely on this. Because the studies were not being done to determine the effects of the radioactive iron or calcium on the individuals. The implication of or benefit must have been intended to indicate that we find there was a deficiency, we are going to correct it. And if you are calcium deficient, we will give you the proper calcium supplementation. If you are iron deficient, we will give you the proper iron supplementation.

The reason for the blood samples was not to look for changes in the blood cells or any other physiological parameters. It was used to find out how much iron was absorbed, how much was made into red cells, how much was excreted. And that was the purpose of the study.

I think it's important to differentiate this cold war mentality from the medical stuff. There was nothing associated with the fact that this was a cold war period that led to these studies being done. These were because people were concerned about nutritional balance in humans in children, and that was the motivation. It was not in any way——

Mr. MARKEY. Except to this extent, Dr. Brill. We must remember here that is an Atomic Energy Commission contract. This is not a contract which is coming out of Harvard or MIT by their own funding. This is an Atomic Energy Commission study being conducted. And why shouldn't it be, then, even retrospectively, honest for us to admit that it was part of the cold war era.

That the Atomic Energy Commission was informed of all of these radioactive isotopes, these radioactive experiments, and that as

they spread through institution after institution, agency after agency across the government, that it all went back to this central need of the Federal government to understand the effect of radiation upon our citizens. And that there were retarded children, there were prisoners, there were elderly who were experimented upon, told that their health might be improved, the worst that would happen is that it would have a benign effect. But in reality, it was really meant to benefit others. That is, it was meant to be scientific research that once you learned what the impact was upon these children, it could be used to benefit others. And that there was, as a result, a responsibility to these children to do continued medical follow-up to ensure that their health had not been harmed.

Why is that not a realistic analysis of what was going on at that time, doctor, given the paranoia at the time, given the over-reaching concern that everyone had about Godless, atheistic communism and the extent to which we would have to go to battle that against them. Put us back in the' 40s now, doctor, and tell us why that wasn't what it was all about.

Dr. BRILL. Well, there is no relevance to anything I can think of in terms of cold war options that would come out of a study of this kind. The only thing you'd learn from the study of this kind, is what are the iron and calcium requirements in people of this particular age so that you could guaranty a minimum nutritional requirement.

Mr. MARKEY. Was it deceptive, doctor, to leave out the word "radioactive," in your opinion?

Dr. BRILL. Oh, yes, I think that in retrospect it was.

Mr. MARKEY. Was it deceptive by the standards of the time to leave out the word "radioactive"?

Dr. BRILL. Apparently not, or else they would have kept it in there.

Mr. MARKEY. Oh, doctor, the reason they left out the word "radioactive" is that they knew that the word itself was radioactive. They kept it from the parents. They kept it from the students. They kept it from, not only here at this institution but from across, across the Nation. They kept it from all these people who were being experimented upon so that there would not be a backlash. Why don't you just admit it? You can admit it now. That was the period. That was the time.

Dr. BRILL. Perhaps so, but let me just say——

Mr. MARKEY. If the President of MIT can apologize, admit that it was a mistake, why is it so hard? What causes people who are in the scientific community, now that the cold war is over, still so much difficulty in looking back and admitting that mistakes were made, that there were secrets that were kept from those who were experimented upon? Why is it so hard?

Dr. BRILL. I am just trying to differentiate those in which that was truly the case, and I'm sure there were circumstances like that, and we all know that it's coming out that those kinds of things were done.

However, this does not fall into that category. This was wrong. Informed consent was wrong. They left out the word "radiation", and they should have included them, because that was the only risk associated with those studies.

But they were not conducted because of the cold war mentality. They were conducted because the scientists wanted to understand nutritional requirements. It's completely different than a cold car mentality, I believe.

Mr. MARKEY. Well, my opinion is that this is wrong, just plain wrong.

Dr. BRILL. Of course it's wrong.

Mr. MARKEY. To have kept this information away from the parents, away from the children, and it is time for us to admit it across all political and scientific lines what was done at that time in the name of national security. Thank you, Senator.

The CHAIRMAN. Just, finally, Mr. Dyer and Mr. LaRocque, did you have a sense, picking up from what you said earlier, that if you participated in this program that you knew was different from what the other children were participating, that in somehow your life here would be somewhat better, that you might have a chance to get out a little bit, attend a Christmas party, maybe, go to a ball game, do something that would break the routine and the monotony? Was that in your mind when you involved yourself in the program? Was that what this whole program sort of meant to you, Mr. LaRocque?

Mr. LAROCQUE. Yes.

Mr. DYER. That did involve it, because I wanted to get out, out of the place here and go somewhere different, to have something to do.

Mr. LAROCQUE. Can I ask one question, please?

The CHAIRMAN. Sure.

Mr. LAROCQUE. To this gentleman here. Nothing personal. But if you had your son here, would you have allowed this to happen, knowing what you know about radiation?

Dr. BRILL. Well, I have, you know, many of us in medicine, when we are investigating new phenomena will take radioactive tracers and study ourselves. I've done it so many times.

Mr. LAROCQUE. But you didn't answer my question directly. I want to know, if it was your son, would you have accepted it? [Applause.]

Dr. BRILL. Knowing what I know now, I would. But at that time, I don't know. At this time, I think the radiation risks from the kinds of doses that were being used are in the noise in terms of biological effect. I don't think any hazard in terms of radiation damage would occur from the kinds of doses that were received. And if I was—the way I think I am, I'd said yes, honestly, yes.

Mr. LAROCQUE. But I'm putting myself, and I want you to put yourself in my shoes, his shoes—I will get back to this, please.

Dr. BRILL. Could I enlarge upon it, though?

The CHAIRMAN. Everyone is free in this hearing to make additional comments, but I think that point has been made very well. I think you responded to it earlier. That's okay.

I want to thank you, thank you all. I just want to repeat what we said earlier. I know Congressman Markey and myself, I know I speak for the overwhelming group, not just our Committee but Congress, they will be of help and you have really helped us very much by your comments. It has been a real service, real, real service. We want to thank all of you. And if you have additional com-

ments you want to add, everyone is free to add those. We want to thank you all very much. Thank you.

We will go to a second panel here.

We will be in order. Everyone was enormously attentive to our first panel, and we want to extend all our courtesies here to our next panel as well. We will ask those that do have conversations, if they would be good enough to take them outside of our meeting room this morning.

We will ask everyone if they would be good enough to take the conversations out of the hall. Thank you.

Our next panel will begin with statements by officials representing the government agencies in the radiation experimentation, investigation currently under way by the Administration, critical of determining who was affected by these research studies.

I am pleased to have Dr. O'Toole from the Department of Energy, Dr. Soper from the Department of Defense, Dr. Albert from the Department of Veterans Affairs, Miss Baldwin from the National Institutes of Health. These officials have come from Washington to discuss the policies and procedures being implemented to ensure that research records are released and documents related to radiation experiments are made available. The Committee expects that appropriate informed consent will be utilized in all the current research studies.

Our final three witnesses represent the institutions involved in the radiation experiments, research in the' 40s and' 50s, Dr. Litster of MIT, Dr. Adelstein of Harvard Medical School, will discuss the nature and purpose of the research and their plans for identifying research participants and current institutional policies related to human subjects research.

Mr. Misilo is the chairman of the Task Force to review the human subject research, will describe the Fernald School in an effort to identify participants in the radiation experiments and compare and contrast the procedures used in the' 40s and' 50s to those today when using human subjects in research experiments.

So we will start off with Dr. O'Toole.

STATEMENTS OF TARA O'TOOLE, M.D., DEPARTMENT OF ENERGY, WASHINGTON, DC; GORDON SOPER, M.D., DEPARTMENT OF DEFENSE, WASHINGTON, DC; MARTIN ALBERT, M.D., DIRECTOR OF MEDICAL RESEARCH, DEPARTMENT OF VETERANS AFFAIRS, WASHINGTON, DC; WENDY BALDWIN, M.D., ACTING DEPUTY DIRECTOR OF EXTRAMURAL RESEARCH, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC; J. DAVID LITSTER, PH.D., PROFESSOR OF PHYSICS; VICE PRESIDENT AND DEAN OF RESEARCH, MASSACHUSETTS INSTITUTE OF TECHNOLOGY; JAMES ADELSTEIN, M.D., HARVARD MEDICAL SCHOOL, CAMBRIDGE, MA; AND FREDERIC MISILO, JR., CHAIRMAN, HUMAN SUBJECT RESEARCH REVIEW TASK FORCE, DEPARTMENT OF MENTAL RETARDATION

Dr. O'TOOLE. Thank you, Senator.

The CHAIRMAN. We are grateful to all of you for joining with us. I think as Congressman Markey and I have stated, we are enor-

mously impressed by the steps that have been taken by Dr. O'Leary and the President just after the announcement by Dr. O'Leary, brought together various agencies. I think that we must keep in mind initially as we go through this process we will probably find that outreach is going to have to go deeper and further than perhaps was initially was understood. And we are very mindful that there is a process and procedure moving ahead by the Administration.

We understand the role that is being taken by the Executive Branch. We obviously have a role and we want to cooperate in every way, work with you. But we want to make sure, like you do, that the job is done. And Congressman Markey and I are enormously grateful for your being here with us.

As you know, there is enormous interest and enormous concern about this in terms of families. You heard our two witnesses. And to the extent that people can have some kind of an understanding and awareness about the nature of the risk and what needs to be done in terms of their own lives and the lives of their families. It is just incredibly important. So we want you to be doing what you should be doing and let us get busy with the Task Force. But we also want to try and make sure that people here in our State, across the country, have as much information as possible.

Dr. O'Toole?

Dr. O'TOOLE. Thank you, Senator. Congressman Markey has already noted your longstanding interest in these issues and your leadership in matters of bioethics. And Congressman Markey, of course, in his Committee in the 1986 report on human guinea pigs revealed for the first time the government-sponsored experiments on ionizing radiation which have revealed a number of disturbing questions about the ethical and scientific propriety of these experiments, questions which previous Administrations have failed to adequately answer.

I would ask that my written statement be entered into the record. With your permission, I would like to outline what the Clinton Administration is doing on matters of ionizing radiation in human experiments.

On January 3rd the White House convened a meeting of a number of Federal agencies who have interests in ionizing radiation experiments on humans. And since then we have had a flurry of meetings involving high level staff from the Department of Energy, the Department of Defense, the Veterans' Administration, NASA, Health and Human Services, CIA, Department of Justice, and other involved Federal agencies.

We have determined to do the following: There will be established an interagency working group on human radiation experiments. This working group will consist of the cabinet officers of the relevant agencies that I just named. And under that working group will be five subcommittees, which I will outline in a moment.

The purpose for the interagency working group will be to determine the extent of human experimentation with ionizing radiation that raises questions, scientific and ethical propriety, since 1944 to the present.

The interagency committee will also determine whether further medical follow-up or assistance might be needed to aid subjects of

these experiments or their descendents. And third, the interagency cabinet group will recommend to the President any changes or additions that might be needed in the current Federal guidelines to guaranty the proper ethical procedures are in place to guard human subjects of experimentation.

There have also been formed six subcommittees working under this interagency working group, the first of which is the Communication Working Group. This group is responsible for outreach with the public, including the maintenance of the 1-800 hotline that was set up by Secretary O'Leary for the Department of Energy and is now capturing calls relevant to all of the Federal agencies.

Since December 24th we have received approximately 12,000 calls on this hotline. About half of them are from veterans and about 25 percent of all of these calls seem to have to do with people who might have been subjects of experiments involving ionizing radiation. We are moving to expand the hotline as quickly as possible so the calls can be answered promptly, and hopefully by close of business today we will be answering calls as they come in. There has been a backlog due to the volume of the calls that we have been receiving, and we ask the public's patience in taking the calls and getting back to you.

The second subcommittee is the Subcommittee of Congressional Affairs. The Administration intends to work closely with and involve the Congress in determining the appropriate responses to the findings the interagency group makes.

The third Subcommittee is the Legal Working Group. This group is now gathering information on responses to other claims from groups such as the people interred, the people of Japanese decent who were interred during World War II, the "Down-Winder" suits and so on and so forth, so that we have a codified index of other past Federal responses to wrongs of this sort that have been raised by these experiments.

There is also a record collection retrieval working group, and this Task Force is busily trying to devise the procedures and processes for finding, collecting and inventorying the records pertinent to human experimentation that will be necessary for review.

Let me note that this is an enormous task. Understand that we are trying to capture documents which now span half a century and will involve virtually the entire Federal government. Some of these documents may be in the nature of Federal contracts or records held by government agencies currently. Some of them may be documents now in the hands of government contractors for universities, for private individuals, or they may be located in archives. There is no central index to these records. There is no easy method to find a way of what records we need and where they are now. But we are putting together the processes for each agency to follow. We are going to make these processes as consistent as possible. And our intent is to make all of these records public as soon as we possibly can on a rolling basis as they come in. We will do everything necessary to respect and protect the privacy of the subjects involved, but the whole purpose here is to make public the whole story on these experiments.

The next working group is the Subcommittee on Ethical and Scientific Standards. This subcommittee is putting together rec-

ommendation for the Interagency Task Force on the Advisory Committee on Science and Ethics. This is to be an independent technically-based Committee consisting of experts in the fields of ethics, medicine, law, radiobiology and so forth who will review the records of these experiments and make appraisals of the scientific and ethical propriety of these experiments. They will also, as they deem necessary, make recommendations to the Interagency Task Force regarding what changes in the current human experimentation guidelines ought to be considered.

It is expected that 6 months after the Independent Advisory Committee is formed it will issue an interim report to the cabinet level offices, and 1 year after it is formed, hopefully we will have the final report in hand.

Understand that we do not yet know the size of the universe of records that we are seeking to recover, nor do we know how big a task to view and inventory and appraisal of these records will be. If it looks 6 months from now that we can't possibly accomplish this review task in a year, then we will make provisions to continue it as long as is necessary to get to the bottom of this.

Let me State a few words as to why we are undertaking this task which is, as I said, a very difficult one, a very ambitious one, and is now involving many very busy people from around the government. We are doing this, first of all, because the cabinet secretaries involved and President Clinton believe that it is critically important to do right by the subjects of these experiments and their families.

We are going to make every attempt to notify those subjects still living and their descendants, if at all possible, to acknowledge the contribution that these people made. To acknowledge that on behalf of the American public. To consider what further medical follow-up or assistance might be of help to these subjects and their families, and to, as I said, consider what we might do to avert any future abuses of human dignity or scientific propriety.

Let me speak for a moment as a physician, if I might, Senator. I think it is important that we recognize that science has brought many benefits to this country, and indeed to the world, over the past decades. And the value of radiation as a diagnostic tool and as a way of treating diseases has to be recognized. Many lives have been saved, including that of my own father, as a consequence of the benefits of radiation.

We are very aware, those of us who have been working night and day on this issue for the past weeks, we are very aware of the enormity of the task that we confront. We are also very aware that there is going to be a lot of disturbing news revealed in the future, and that this is going to be painful in some regard.

If mistakes were made, let's admit it. If wrongs were committed, let's acknowledge them, and see what we can do to make amends. And if we can do even better in the future, then let us put the processes and practices in place to ensure that we do so.

Our hope is that the discussions and the debate around these matters will be serious and thoughtful, that the public will be patient as we strive to get all of the information out as quickly as we possibly can, and that as we start to tell the truth, painful as it might be, we in the Clinton Administration will start to give the

American people good reason to believe that the government is coming clean and telling the truth and is worthy of trust.

Thank you, Senator.

The CHAIRMAN. Thank you very much. Let me just point out, as you mentioned, I think down to personal terms, many families benefited more from research. You know, we have, I know my own family, the renal scans, a member of my family that has used that. I think the value of a stress test is something that I've had a member of a family not too long ago and even the bone scans that my sister Eunice had a bad automobile accident. So I mean, I think I think most people in this room one way or the other have lives that have been touched by it and I think it's appropriate that you pointed out that kind of perspective. Very good.

Go ahead, Dr. Soper.

Dr. SOPER. Senator Kennedy, Congressman Markey, Commissioner, it's a pleasure to be here representing Mr. Less Aspin, the Secretary of Defense. And we are an active participant in the interagency process that Dr. O'Toole just described.

The Department of Defense has responded quickly and aggressively once this issue came to its attention 2 weeks ago. We are providing senior level people to work on the subcommittees that Dr. O'Toole described in the interagency process. Perhaps the reason I am here today is because of the five, I'm on two of them, and I've witnessed the process that's begun from the beginning.

Mr. Aspin has provided to the entire Department of Defense early guidance on how to proceed. He has put into place a series of high level officials to respond to this. Dr. Deutsch, who many of you know is the MIT provost, is the overall senior DOD official, and Dr. Harold Smith, Assistant for the Secretary of Energy for Atomic Energy, my boss, also an MIT graduate, to help structure the process.

And I'll be happy to respond to questions with respect to the details of what the Department is doing. I agree with Dr. O'Toole. It is a very complex, a very difficult process. We have begun that long process, and Mr. Aspin wanted you to know he expresses his personal concern about these reports, and has committed the Department of Defense to explore all avenues available to us to reveal any information within our jurisdiction that might shed light on this matter.

Thank you very much for the opportunity to speak.

The CHAIRMAN. Dr. Albert is from the Veteran's Administration.

Dr. ALBERT. Dr. Martin Albert, Director of Medical Research for Veteran's Affairs. I have no prepared statement which you have in your hands, but I would like to make a personal comment. On this topic I think we need facts. I appreciate the fact that you Senator Kennedy and you Congressman Markey are holding these hearings. As a scientist, I think that we should draw conclusions only after we've obtained the facts, and that's what I presume these hearings are for.

We must find out if something wrong was done. We have a personal and institutional moral responsibility to find out if something wrong was done, and if so, to do something about it. But we must also recognize the benefits of the research that was done with radioisotopes.

Within the VA, the CT scan was invented. Within the VA, a Nobel prize was given for the development of the basic radioisotope research underlying radioimmunoassay. And of course Senator Kennedy and others have already spoken about the benefits of radiation therapy for cancer.

Despite these benefits, no one should do inappropriate or unethical research ever. Not now, not then. Nor should we condone it.

There was a question that was asked of the previous panel, and if you would allow me, I would answer that question, on behalf of myself as Director of the Medical Research. Senator Kennedy, you were asking the question about the current practice for informed consent.

All research in the VA, all research involving human subjects conforms to an explicitly rigorous set of standards concerning informed consent and protection of subjects. We have a detailed and comprehensive system which includes reviews at several levels. A scientific review and a separate human study—human subject protection review. The human subjects protection review includes review by the committee which includes representatives of the community, rabbis, priests, legal representatives, and ethicists.

In addition, because I have a special interest in medical ethics, when I took over this job a year ago, during the past year I developed a special unit within the VA which is labeled ethics and values in medical research. And we have on top of this informed consent procedure, special concerns about these issues so that no research on human subjects is done in the VA, including radioisotope research, which doesn't take these issues into account.

The final comment I'd like to make has to do with Secretary Brown's response, which has been quick and efficient and effective. He has sent out a message throughout the entire Veteran's Administration system saying that he wants all records, all shreds, all scraps of records, wherever they are held, research records, clinical records, regarding radioisotope research going back to this time that we are talking about to be made available, collated, organized, so that we can give you that information, provide your Committee with the facts. Thank you.

The CHAIRMAN. We will come back to that. But that's enough of a response.

Ms. Baldwin.

Dr. BALDWIN. Thank you, Senator, Mr. Markey, Commissioner Campbell. I'm Dr. Wendy Baldwin, acting deputy director for Extramural Research at the National Institutes of Health, part of the Health Service, one of the components of Health and Human Services. With me today is Dr. Gary Ellis who is director of our Office for Protection from Research Risks. While I submitted a prepared statement, I'd like to read parts of that for the hearing today.

First of all, HHS is fully participating in the procedures that Dr. O'Toole outlines regarding our Interagency Task Force and I'd like to reflect on the comments she made about the enormity of the task of locating the necessary records.

Dr. Albert's correct that what we need are facts. And what we must do now is obtain those facts and obtain records from much of the work supported by the public health service. The records of the most interest, those regarding informed consent, research pro-

tocols are the subjects and so we are going to do a rather significant effort in order to accomplish this.

NIH, in particular the National Cancer Institute, has conducted longitudinal studies on radiation exposure of Chernobyl victims, and follow-up studies of patients who received radiation as a part of their treatment regimen. CDC has also conducted studies of the human health effects of occupational and environmental exposure to radiation.

But as has been reflected so often this morning, one of our concerns is the strategies that are in place for the protections of human subjects. What that situation is today, and what it has been like in the past.

A brief chronology of Federal activities regarding the human subjects protection, NIH anyway, begins in 1953 with our clinical center when they produced the first U.S. Federal policy for the protection of human subjects. This policy and the Committee that implemented it was an early step in the research review mechanism known as the Institutional Review Board, or the IRB that is so fundamental to our current system of human subject protection throughout the United States.

On February 9, 1966, the Public Health Service issued a policy that provided broad protection for participants in research supported by the Public Health Service. The Department of Health, Education and Welfare, predecessor to HHS, regulations protecting human subjects first became effective May 30, 1974. This is certainly an era, Senator Kennedy, which you are well familiar with, since you were critical to this stage.

The 1966 policy and the regulations that followed in 1974 were based on the concept that freely given consent to participation and research is the cornerstone of ethical experimentation involving human subjects.

The regulations established the Institutional Review Board, IRB, as the major mechanism through which the adequacy of informed consent process is checked, and the rights and welfare of human subjects are at once protected.

In 1981, in response to reports and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, HHS promulgated revisions concerned with important additional details of what an IRB is expected to accomplish and the procedures that it must follow.

In 1991, the core of the HHS regulation was further revised, was adopted as the Federal Policy for the Protection of Human Subjects. This is the so-called common rule. It was promulgated by 16 Federal departments and agencies including those represented here today. This policy is designed to make uniform the human protection system at all relevant Federal departments. This policy is a framework in which investigators, Institutional Review Boards, members, and others, can ensure that serious efforts are being made to protect the rights and welfare of research subjects. The regulations also hold researchers and IRBs publicly accountable for their decisions and actions.

The Department of Health and Human Services Office for Protection for Research Risks oversees the implementation of this policy in all HHS facilities as well as domestic and foreign institutions or

sites receiving HHS funds. OPRR requires that each HHS agency and extramural research institution that conducts or supports research human subjects sets forth the procedures that it will use to protect human subjects in a policy statement called an "assurance of compliance" or commonly referred to as an "assurance".

This is a formal commitment to widely held ethical principles to the HHS regulations for the Protection of Human Subjects. It shows institutional procedures adequate to safeguard the rights and welfare of human subjects, and the terms of the institution's assurances are negotiated with the OPRR. Let me turn briefly to the responsibilities of Institutional Review Boards.

IRB review is responsible for ensuring that risks are minimized and reasonable in relationship to the anticipated benefits, that there is an informed consent, and that the rights and the welfare of subjects are maintained in other ways as well.

Research investigators have a fundamental responsibility to safeguard the rights and welfare of the people participating in their research activities. In addition, our society has decided by law that an objective review of research activities involving human subjects by a diverse group of individuals is most likely to protect human subjects and promote ethically sound research.

IRB's are generally composed of members with expertise in science, ethics, and other nonscientific areas. This diversity fosters a comprehensive approach to safeguarding rights and welfare of human subjects.

Mr. Chairman, on February 9th, this system of protecting human volunteers in research supported by HHS enters its 29th year of continuous oversight. So in closing, we want to assure you that the protections in place are designed to preclude the very problems that we've gathered here to discuss.

The CHAIRMAN. Thank you very much.

Dr. Litster.

Mr. LITSTER. My name is David Litster. I am professor of physics and vice president and dean for research at the Massachusetts Institute of Technology. Those of you who can read my name tag here may wonder if I'm here under some false pretenses. I am not an MD. I am a Ph.D. My research is in the area of condensed metaphysics and so I am not an expert in the subject of health business.

However, it is a subject which I have heard a great deal about in the past few years. I'm here to tell you how MIT has responded to the recent series of newspaper stories, stories which concerned research with human subjects in the 1940s and' 50s in which radioactive materials were used and which involved MIT staff or students.

I first learned about this research in the Boston Globe when the story appeared the Sunday after Christmas. My reaction to that story was very similar to that of Representative Markey. I was shocked and disturbed. And like Congressman Markey, I asked myself, well, what could I do and what could MIT do to help in this situation. I do not subscribe to the theory that what you don't know can't hurt you. And therefore I decided that the most constructive thing that we could do is to attempt to unearth all of the facts and all of the information that we can find about these experiments in

order that we could share it with the people if we needed to have that information.

When I got to work the following day, I started to make a few phone calls to begin to learn what had gone on. And shortly thereafter, MIT President Charles Vest called me and asked me to undertake a review.

The purpose of that review is to determine and understand the following matters: First of all, what was the nature, purpose and the results of the research.

Second, what was the amount of radiation that the subjects were exposed to, and what risk did that entail, both by the standards of the 1950s and by current standards.

Third, any information which might help to identify the subjects, in order that that might be communicated to the Massachusetts DMI Task Force and the subjects informed.

And last I was asked to review what were institute policies regarding the use of human subjects in the research at that time and to contrast and compare them with current MIT policies. President Vest has expressed his concern and has issue the following statement to the press which I would like to read to you.

And I quote, "I was sorry to hear that at least some of the young people who participated in this research and their parents apparently were unaware that the study involved radioactive tracers. People should not unknowingly become the subjects of research studies of this type."

We have had in place for more than two decades at MIT numerous safeguards and approval processes that assure informed consent of human subjects in any research. It is important to recognize that the purpose of these studies was to improve the understanding of nutritional processes in order to promote the health of young people. And the radiation exposure appears to have been well within even today's limits.

We have started to examine the archival records of MIT in order to learn as much as we can about these matters. I have recently completed a review, essentially completed a review, of the research of the Fernald School pupils which was conducted by MIT professor Robin Harris. This research required the addition of minute amounts of radioactive iron and radioactive calcium to their food in order to determine how iron and calcium were taken up in their diet.

Dr. Brill has summarized, I think, in a very clear way what was the motivation and purpose of this research. I don't want to take time to repeat what he said.

I have a long prepared text which we entered into the record and may be consulted and it's been furnished to the press. I don't have time to read it here. I just wanted to touch on some of the high points.

First of all, I'd like to provide the research into two parts. There was research involving radioactive iron as a tracer and then several years later there was research involving radioactive calcium as a tracer.

The subjects of the radioactive iron were 17 youths from the Fernald School. We've heard from Dr. Brill about what was the purpose of that research and it was motivated by the fact that two

cereals which the people often ate, one was rolled oats and one was farina, which is the name for Cream of Wheat, had contained a phytate chemical which had been suggested by previous experiments interfered with the uptake of iron in the diet. And the purpose of the experiments was to understand if that was the case.

I can tell you the result was—the general conclusion was that the rolled oats was no worse than farina, which perhaps pleased the Quaker Oats Company, and that the general principle was established that iron supplements were much better given to people between meals rather than with meals.

In addition, children who were living in institutions, such as the Fernald School, could continue to eat oatmeal, which I suspected many of them did in rather large amounts, without concern for negative dietary effects, so far as iron was concerned.

The calcium experiments calculated—conducted a few years later involved 36 pupils at the Fernald School, each of whom received two breakfasts containing milk, which had a radioactive tracer in calcium, and again, the purpose was to understand if the phytate chemical interfered with the dietary uptake of calcium. The conclusion was that with the oatmeal accompanied by sufficient milk, that was not a problem. If the amount of milk was rather small, that could be a problem. Most American diets in fact have enough calcium that that's not the difficulty.

The third set of studies involved the direct injection of small amounts of radioactive calcium to nine youths in the Fernald School and one adult. The purpose was to determine what happened to calcium once it entered the bloodstream. It showed it went very quickly to the bones.

And this research using radioactive calcium tracers to understand calcium metabolism really laid the foundation for much subsequent work, research on osteoporosis. Now I'd like to turn to the question.

The CHAIRMAN. Well, just a minute. This is all being sponsored, though, by Quaker Oats, wasn't it, the research?

Mr. LITSTER. The iron research was sponsored entirely by Quaker Oats. The calcium——

The CHAIRMAN. Well, I think we got to understand besides, you know, how we are appreciating diets and how this goes on to benefit osteoporosis, I mean, we are talking about a commercial operation that is effectively funding one of the professor's research program that is taking place out here and that is being done to make a buck in terms of Quaker Oats. I mean, it has got these other benefits that go on, but I missed in terms of your presentation the fact that the hard reality, and that is very proper kind of a commercial operation is funding research through MIT, as they do, and that was taking place here under the circumstances which have been outlined in the previous—by the previous witnesses.

Mr. LITSTER. That's correct. And as it turned out, I think the results of the research were pleasing to Quaker Oats. They had no way of knowing——

The CHAIRMAN. Oh, that's good for Quaker Oats. I hope they do very well, but that isn't really, the substance, is it, about what this whole hearing is really about, whether Quaker Oats had a good investment or whether they have done well commercially.

Mr. LITSTER. Well, no, that's not what interests us.

The CHAIRMAN. I want to get the rest of your testimony, but to the extent that we can focus on what you understand to be the essential public policy issues which have been outlined very well by Dr. O'Toole and the others, particularly the victims here today, is what we are really interested in hearing about MIT.

And so to the extent that you can—I know you are new to this process—to the extent that you will include the whole statement in the record or to the extent that you can give us at least an insight into it and MIT's perspective, which I think reflected Dr. Vest's excellent comment and statement on it, I think would be useful.

Mr. LITSTER. All right. I think the public policy issues at the time have been rather well covered by the others. I'd be happy to give you MIT's perspective on that. I can also give you the facts that I determined on how much radiation these people were exposed to, if you are interested.

The CHAIRMAN. I think that's very important.

We want to find out, these people want to find out, and you are an expert on this issue. I gather, at least, and that I think is very, very important, so people will know, at least from your professional viewpoint, the extent in looking back and studying these matters, outside of the aspects of whether it did well in terms of cereal, you know, what has been the health, how much danger. I guess a lot of people want to know from you about what the health dangers are on it. I think that is important.

Mr. LITSTER. Let me give you the bottom line on that.

The CHAIRMAN. Good.

Mr. LITSTER. If I don't tell you enough, you can probe further.

So far as the iron experiments are concerned, it's a rather complicated deal to figure out how much they were exposed to. And the fact that the ingested radiation on people depends very much on your weight, your body weight. Just the same in effect on the ingestion of alcohol. The participant who weighed the most in these studies got the least exposure dose of radiation. The one who weighed the least got the most.

I found in analyzing all the data that was in the paper that the exposures range from 170 millirems to 330 millirems with an average of around 230. Now, I don't want to go into the complicated deal of what a millirem is. That is in effect explained in my testimony, written testimony. But the fact is that 300 millirems is the natural amount of radiation which we are all exposed to by living in Boston.

If we were living in Denver, Colorado, we would be exposed to 400 millirems each year. So what these participants in the iron experiments received, which was something that was comparable to the amount of natural background radiation or exposure.

If we turn to the calcium experiments, it turns out the exposure was much less. The exposures in the calcium research were all of the order of 12 millirem or slightly less. And again, to put that in some kind of a context which I think we have a feeling for, 12 millirems is the radiation dose you get going on an airplane flight to California and back.

And if Mr. Dyer and Mr. LaRocque could furnish me with their birthdate, I believe I have enough information at MIT that I could

tell them precisely how much they were exposed to. And we of course intend to furnish that kind of information to the State Task Force for this kind of information being given to them. Now, perhaps——

The CHAIRMAN. Just what is the cumulative effect of this? I mean, you know, we all find out, I know we are dealing, you know, about the tolerable amounts in terms of radiation. It's a very dicey kind of issue at best. But what is your professional judgment that the cumulative amount that each of them took. I know you have light weight and heavier weight individuals. Let's take the worst case scenario and that is, as I understand from your papers, you don't have the names—you've got the weights, am I correct?

Mr. LITSTER. We have the birthdates and the weights.

The CHAIRMAN. And the weights, okay. So if you took the worst case scenario, the person that weighed the least and was exposed for the longest period of time, just from your professional—you are not a doctor, as I understand it, you mentioned yourself. But what would you say, from your own professional degree of health risk to them?

Mr. LITSTER. Well, my understanding of this is that when you express the exposure in terms of these units call millirems, that you then have numbers which you can directly compare from all sources. And so someone who received, worst case you mentioned was 330 millirems from eating iron. That is the total cumulative effect. And it's essentially the same within ten percent of what you would get for total cumulative effect from background radiation in 1 year by living in Boston.

As to what are the medical and biological effects of that, with such low doses of radiation, it's very difficult. But there are generally accepted figures for the National Committee, the Council on Radiation Protection, which is that that sort of dose, administered to a child—children are more sensitive to radiation—would experience an extra risk of contracting cancer of about one in 2000. That would be compared with the normal risk that everyone has of one in five of contracting cancer.

The CHAIRMAN. But that's not the standard that we are looking at in terms, for example, pesticides, it's one in a million standard.

Mr. LITSTER. Yes.

The CHAIRMAN. So you are talking about one in 2,000. I mean, you are the professor here, but don't try and jam us about the number of people that are going to die of cancer. I mean, I'm up to speed on that stuff, too.

So it isn't just the one in 2,000. You are talking about, at least, in terms of administration—I want to get on with the other witnesses—but we are looking at in terms of the kinds of residues, particularly for children, as you pointed out, who have much slower absorption and different absorption level and their whole biological development systems are much more sensitive in terms of the kinds of absorptions that they have in terms of all of these, pesticides particularly.

So just to come back to the basic kind of factor, your professional—and of course we will have others that will comment on it, but I would like to hear yours, is based upon what you understand

the length of time that they took it is that basically, for those that are involved in the Fernald School, is basically minimal?

Mr. LITSTER. I am not quite sure I'd go quite that far with the iron. With the calcium, certainly.

The CHAIRMAN. How would you step it up? You use the word. I'd like to move on.

Mr. LITSTER. It is hard to find a——

The CHAIRMAN. It is worthwhile following up on.

Mr. LITSTER. I am much more comfortable with a mathematical statement, which is it did expose them to certain risk of cancer.

The CHAIRMAN. Well, it did. OK. That's good enough. Good.

Mr. LITSTER. Well, I can simply very briefly tell you that at that particular time MIT had no formal review processes in place to examine these types of experiments. It was left up to the ethical standards. And currently you have heard from Dr. Baldwin what the current procedures are. So things have changed a lot from that time.

The CHAIRMAN. I think that's enormously important, all the way through. I think we want to find out what has been done, you know, in the past, that we have not found out and be sure that nothing is happening today. And I think you have commented. Dr. Adelstein?

Mr. MARKEY. Could I just add, just following up here on Dr. Litster for a second, if I may, before we move on.

Just so I can understand, you know, what the point is, earlier we were hearing Dr. Brill say that he would be willing to take those doses, even today. And that's fine.

But it leaves a misimpression, and the impression it leaves, well, it is not harmful. What you are saying is, Dr. Litster, is that there was in fact a higher likelihood of contraction of cancer that would be incurred by those children from that time on, because they had been experimented upon, is that correct?

Mr. LITSTER. Yes, I think that's the currently accepted opinion. I would defer to some of the experts on that, but I believe the conservative view is that any exposure to radiation does convey some additional risk of cancer.

Mr. MARKEY. So the letter of consent, then, that said that we expect this to actually lead to an improvement of the boys, was not only misleading, it was false. By the standards of the science at the time, they knew that there could be and probably would be, adverse consequence, maybe marginally adverse, but the words benign or improvement should not have been used at all in communication with the parents or conversations with the boys at that time, do you agree with that?

Mr. LITSTER. I don't want to say anything in defense of the procedures that were involved. My opinion of them is that they were not appropriate.

Mr. MARKEY. But I mean what I think what everyone here wants to know, doctor, is what people's concerns are, is whether or not the form which did not use the word "radioactivity", did not inform that there could be adverse consequences for the boys, was inadequate not only by the standards of today, but even by the standards of that time in terms of the experimentation being conducted here at the Fernald.

Mr. LITSTER. Well, I would put it this way. At best, what that form secured was consent. It did not secure informed consent.

The CHAIRMAN. I think that answers the question. Thank you.

Dr. Adelstein.

Dr. ADELSTEIN. Thank you, Senator, Congressman, Mr. Commissioner. I'd like to begin by expressing my sympathy to the former students at the Fernald School and their families. We have certainly heard from Mr. Dyer and Mr. LaRocque how upsetting these events have been for them. And I want to say to them and to the other Fernald families that I and others at Harvard take your concerns with the utmost seriousness, and we are working cooperatively with the State Task Force and other authorities to help shed light on the situation.

Serious questions have certainly been raised about the Fernald research in the 1940s and the 1950s, questions involving possible risks of exposure to radiation and what we now know to be the inadequacies of the consent obtained from the participants in the research or from their family, and the fact that this population was used in the first place.

I'm not here today to try to answer any of those questions, since we are still in the process of gathering the relevant facts and understanding them in historical context. But I am here to say that we are determined to cooperate fully with the Federal and State authorities in order to help bring relevant information to light and make progress in answering the important questions that have been raised here this morning.

Today, we have already begun to search our files for relevant records that would help us in learning more about what did occur at Fernald several decades ago, who was involved, the nature of their involvement, the possible relationship to our institution, how participants were chosen, what procedures were and were not followed to obtain consent, and what risks if any the research may have involved.

Obviously in situations like this, and our system being as dispersed as it is among the hospital, that it will take us awhile to gather all the records together. But we are in close touch with the several hospitals affiliated at Harvard to see what records they have in their own file.

Now, part of the problem also is that there is in the mix with our files are personal patient records, and we need to separate out these matters of confidentiality from the general issues.

We are working on that at the present moment. Another problem is the fact that research took place sometime ago, and that the person principally involved in the Fernald research who has been identified with Harvard, Dr. Clement Bender, died nearly 20 years ago. Dr. Bender, as many here know, was employed by the Commonwealth as the medical director of the Fernald School for this period in question. He had a special interest in Down's syndrome and in congenital hyperthyroidism and thus was concerned with the possibilities of endocrine abnormalities in mental retardation.

In addition to his duties here at the Fernald School, he held a Harvard appointment through his role as an instructor in neuropathology and psychiatrist at the Massachusetts General, a

Harvard affiliated hospital. And he also held appointments over the years with a number of other Massachusetts institutions.

Now, in addition to the search for the relevant records, we are assembling a group of Harvard faculty, expert in the field of clinical investigation, biomedical ethics, human rights, radiation effects, psychopharmacology and mental health and other disciplines. The committee will examine the use of human subjects and research by Harvard investigators with the focus on the period in question, and with particular regard to such matters as the choice of subjects and volunteers, issues of consent, prevailing standards of practice, and what mechanisms were in place for institutional oversight.

The Committee's attention will be directed in the first instance to particular research projects such as those here at the Fernald School that have recently become the object of public attention.

Now, in addition to that, some recent news reports have raised questions about the standards in place today that cover the use of human subjects and research. We've heard quite a bit about this from this panel, but I'd like to show you that Harvard has strong safeguards currently in place and strict mechanisms for ensuring compliance.

The university and its affiliated hospitals follow these stringent Federal guidelines established more than 20 years ago for review on all proposals to use human being research employing Institutional Review Boards which have a wide range of working reputation.

Generally speaking, the guidelines require scientists and physicians to consider the health of the research participants over all other matters and to obtain fully informed consent of any participant, as well as voluntary uncoerced participation. And I think Congressman Markey has emphasized that fact. We are fully committed to the hearings in these standards and in making sure that they continue to safeguard the interests of all human participants in research.

Thus in closing I'd like to reiterate Harvard's commitment toward working closely and cooperatively with the Department of Mental Retardation and of course with you, Senator, and Congressman Markey, in bringing relevant information to light. And again, to express our sympathy to the former students and families and our commitment to help them and all of us better understand the research conducted almost 50 years ago. Thank you.

The CHAIRMAN. Mr. Misilo?

Mr. MISILO. Good morning, Senator, Representative, and Commissioner. In serving as the chairperson for the human subject research review Task Force recently established by Commissioner Campbell, in light of the recent public disclosure by Energy Secretary Hazel O'Leary of certain research studies in which radioactive isotopes were administered to former residents at Fernald School back in the late' 40s and early' 50s, I'd like to thank you both the Senator Kennedy and Representative Markey for the opportunity to present testimony here today.

Before I begin, I would like to specifically acknowledge, as has already been stated this morning, the long-term commitment that Senator Kennedy has had in advancing and protecting the rights of the disabled throughout his distinguished career.

In fact, as I have already stated, it's a little more than 20 years ago that Senator Kennedy was instrumental in establishing a broad-based national commitment for the protection of human subjects, biomedical, and behavioral research, which worked from 1974 to 1978 in restoring the governmental confidence in medical research in charting the ethically appropriate course for the regulation of such research. Among the charges of the national commission was the development of guidelines for research for fetus, on children, and those institutionalized with mental infirmities, as well as providing guidelines for general research. Many of these guidelines have been promulgated in the form of regulations, all have been proven effective safeguards.

Representative Markey, you have the full commitment and cooperation of the Department of Mental Retardation to work with you in furtherance of your commitment to full and complete knowledge, understanding and make known the full extent of testing within the Department's facilities. I look forward to working with you on the Task Force and I want to express my appreciation for your efforts in this undertaking. The Task Force will review and analyze all research which was used—which used radioactive materials and involved individuals who were residents in the Department's institutions. The Task Force will attempt to identify each individual and provide them with information regarding the research. The Task Force will submit its findings in written form to Commissioner Campbell on or before March 31 of 1994.

The Task Force is comprised of parents, noted leaders in the field of mental retardation, physicians, elected leaders, religious people, human rights advocates, researchers and attorneys. Supporting this Task Force is a technical advisory group of some 25 individuals who will conduct thorough record reviews, research archival materials throughout our institution, and provide expert assistance in their respective fields. Members of the Task Force and the support advisory group have already come together twice to organize the backlog, plan strategy. The Task Force itself will hold its first official meeting tomorrow. We have already established lengthy meetings with the Department of Energy, the Massachusetts Department of Public Health, Harvard, and MIT, as well as a number of hospitals connected with these tests in Boston. In an effort to gain access to relevant materials, we have provided you with a list of the Task Force members and we also invited representatives of your staff to participate in this review.

As you can imagine, the last few weeks have been a whirlwind of activity for those involved, for those of us involved in responding to the questions, the concerns, and the anxieties of hundreds of people who may have been involved in these studies, tests, experiments.

The Department of Mental Retardation has taken the initiative on a number of fronts in light of these disclosures. These include establishing a toll free number which has been staffed with trained individuals to assist callers who think they were involved in the testing.

To date we have receiving over 200 requests and are in the process of responding to each one of these individually. Staff at each of the DMR facilities across the Commonwealth have begun review-

ing medical records dating back to 60 and 70 years ago, along with archival files to determine the extent of testing at each facility. The result of these searches will be forwarded to the Task Force.

We have interviewed already 25 individuals who have information about the testing. These interviews will continue and we expect to expand as more people come forward. A complete review of the materials in the Howe Library located here on the Fernald campus is now underway and will hopefully lead to more definitive and helpful information. We are making every effort to accommodate the request of the media and to keep the public informed of our progress in these matters.

Over the past 2 weeks we have been able to determine with a reasonable degree of certainty the following: The testing and research at our facilities was far more prevalent than we had ever thought or envisioned. Second, that we are currently looking at research that could at a minimum have involved at least 300 of our consumers. Three, as Dr. Litster just described, and as has been presented in his testimony, we believe there has been three additional nutritional studies in addition to the one which was published in the Journal of Nutritional Medicine. All of these additional tests we believe may have involved the use of radioactive isotopes, although we have not obtained written confirmation of these three additional tests from MIT.

We can confirm that some residents from Fernald were involved in the studies in thyroid function, conducted by MIT Clinical Research Center which used radioisotopes. We have not been able to determine whether disclosure of the use of these radioisotopes was made to the residents or to their families.

At this point in our work, clearly we have more questions than answers. We are in the process of sending out over 3,000 letters to families, employees and volunteers, informing them of our activities and asking for their assistance. We are also establishing a resource needs list that will define the staff, materials, consultants, and funds that will be required to complete this review.

One final comment, if I may. The use of individuals with mental retardation from a confined and institutional setting for biomedical research has been well documented in the literature in the past and across the Nation. I would encourage you and this Committee to expand your inquiries to other states as well for I believe that these Fernald experiments are simply reflective of the activities which were quite common for that particular time period in our history.

We must recognize that even with appropriate safeguards, individuals with mental retardation, particularly those who are institutionalized, are vulnerable to being exploited. The fundamental interest at stake here is one's right to privacy and self-determination. The central method for insuring that these rights are safeguarded is through requirement of informed consent in any kind of research.

Clearly the ability of individuals with impaired capacity to understand the conditions and consequences of participation, the requirements, the risks and potential benefits of research activity is a prerequisite to informed consent being given.

Unless this understanding is achieved, can consent of a participant in a research experiment truly be informed? Moreover, participation by the people confined in institutions, as we have heard this morning so vividly described, is likely to result in rewards for special privileges for participation, or perhaps expressed or implied threats for refusing to participate or perhaps still from simply a naive desire to please those in authority.

Therefore, how reliably can one truly draw a distinction from the benefits, privileges, bribery, coercion or a need to desire to please? The research which involved the members of the science club over 40 years ago clearly did not obtain the informed consent of those research participants. These tests serve as a dark reminder of the vulnerability of institutionalized persons with diminished capacity to be exploited, oftentimes in the name of some greater good. Today, thanks to the work of the National Commission for the Deaf by Senator Kennedy over 20 years ago and to increased Federal and State statutory and regulatory requirements, there are many safeguards in place to protect individual rights.

Let us be mindful that those very safeguards which have been in place close to two decades now, came about as a direct result of dramatic public disclosures of abuses in human research involving persons with mental retardation and others in our society who found themselves in positions of powerlessness.

The constant challenge we all face is to weigh whether these safeguards continue to be adequate, for in the final analysis, bringing public attention to a grievous violation of basic expectations of privacy and decency in human research is clearly a role of government officials. However I believe we are all in agreement that our collective responsibility does not stop there. For it requires us to consider these issues after the publicity dies down, in order to determine whether additional protection or safeguards should be enacted.

I would like to acknowledge and thank those individuals who assisted the Department in the last 2 weeks during this very trying time. Peter O'Meara, the facility director here at Fernald and his staff deserve special mention for his usual outstanding effort and professionalism over the last 2 weeks. I again want to extend my thanks to Senator Kennedy and Representative Markey for their interest in these matters, and I assure you that the Department will fully and completely cooperate with you in this matter. The Department is committed to full and complete disclosure of any and all research activities which was conducted here at Fernald and in all other DMR facilities.

Thank you very much.

The CHAIRMAN. Thank you very much for really an enormously perceptive and sensitive kind of a comment about the whole moral and ethical dilemma. You know, you just underline the significance of the captive populations. And you said it very eloquently. This is what we are talking about, in too many instances, captive populations probably in our State and states across the country. I am not even going to get back to looking back at that old consent form doesn't even mention, you know, boys. I mean what we are talking about all the sensitivities that have gone on in terms of the kinds of people that were included in this, in that consent form. It is an

impressive statement in terms of the seriousness which the State is moving and I think all of us in the Commonwealth have to be impressed by what you are doing.

Let me just move quickly down, because we have an excellent panel coming up for our third panel and I want to make sure that we hear from them.

Dr. O'Toole, there have been recent news reports that hundreds of infants were injected with the low levels of radioiodine around the country during the' 50s.

Can you tell us whether any of these experiments took place in Massachusetts?

Dr. O'TOOLE. No, I can't, Senator.

The CHAIRMAN. So we don't know whether they did or they did not?

Dr. O'TOOLE. No, Senator. I have been busy trying to help with the other Administration issues and officials in setting up the process whereby we can collect the records. I haven't finished looking at the records myself.

The CHAIRMAN. OK. Well, can you let us know?

Dr. O'TOOLE. We are very determined to cooperate with Congress and to let you know as soon as we find any information we know regarding these incidents.

The CHAIRMAN. And it has been recently revealed that there were radiation experiments conducted at Vanderbilt Hospital, the prenatal clinic funded by the AEC. A hundred pregnant woman visiting the clinic for prenatal care ingested radiative pills. There was no notice of the experiments, no consent received.

Do you know whether any of those studies were conducted in Massachusetts?

Dr. O'TOOLE. No, I don't, Senator.

The CHAIRMAN. If you will let us know.

Let me ask Dr. Albert, in the earlier comments and testimony we had, Dr. Burrows mentioned I think 148 cases that were, that you have been going through. And he told us that there were, in reviewing the protocols I think he mentioned to us there were 145 of the cases that he talked about in Boston. Are you familiar with that?

Dr. ALBERT. I think what he was referring to was ledger books.

The CHAIRMAN. Yes.

Dr. ALBERT. Files, records. Not specifically numbers of the individuals but documents that he has from the early days of research.

The CHAIRMAN. OK. Can you give us any idea when those will be made available to the public?

Dr. ALBERT. That information is available right now, frankly, to anybody who wants it.

The CHAIRMAN. How would people know whether they are included in it?

Dr. ALBERT. OK. What's happening is that Dr. Belton Burrows and the team of people from the VA are reviewing that and will be sending out information about it first.

The CHAIRMAN. But for anyone that is interested in that, it appears that records of all studies performed at Cushing and the Boston VA Medical Center is approximately 150 ledgers, loose-leaf notebooks, other clinical files from 1949. These include organ

stamps obtained after 1963. But as far as you are concerned, you are turning those over to the Task Force which also those lists are available?

Dr. ALBERT. Absolutely.

The CHAIRMAN. OK.

Let me ask you, Dr. Litster, as I understand the word, there were 23 pregnant women at Boston Lying Hospital injected with radioactive in the early' 50s under the AEC. What did researchers hope to gain from that research, do you know?

Mr. LITSTER. Well, Senator, that is some research which we just started to look into. So what I'm telling you it's preliminary. What they were actually given was red cells which were already labeled radioactive iron and the goal was to understand how iron as a nutrient was transferred across the placenta from the mother to the infant. And there was a follow paper which came out based on the same studies, which was analyzing the data to determine for what period of postnatal life that an infant carries sufficient iron stores in the body in order that it didn't need to receive it in the diet.

The CHAIRMAN. But as your preliminary review indicated, no adverse effects on the mothers and their babies?

Mr. LITSTER. No, it hasn't. My preliminary estimates of the radiation dose they received is that it's very similar to what the Fernald pupils received.

The CHAIRMAN. All right. And is it the intention to identify the participants in the experiments, make available to them information that they have been involved, assuming that they didn't get the kind of adequate informed consent that I think we have seen here this morning?

Mr. LITSTER. Well, I think if the consent were adequately informed, it would be our intention to try and identify the people.

The CHAIRMAN. And you can't now indicate to us when that would take place? But what could you say in terms of—are you going to be doing it at the earliest possible time?

Mr. LITSTER. I think that's correct, yes.

The CHAIRMAN. Are you talking just a few days, weeks, what?

Mr. LITSTER. I would hope in that particular experiment that we are talking within the week.

The CHAIRMAN. All right. Within a week.

Mr. LITSTER. Now, the thing I can't promise you is whether we have any information that would help identify the women. That information is perhaps in the patient records in the hospital which Dr. Adelstein referred to. I'm sure they are working as hard as they can in finding it.

The CHAIRMAN. Mr. Misilo, do you have plans to follow-up or will there be a follow-up of the other students who are members of the science club to make efforts to identify and locate participants in the science club and ensure that they receive appropriate medical follow-up?

Mr. MISILO. Yes, that's our intention, Senator, is to follow-up and identify all of the individuals. We do not have a list, a comprehensive list now. We will work with MIT to locate the birthdays and corresponding birthdays and the weights.

We also have a 1-800 number, as I offered in my testimony, for any individuals who may have been involved in the science club. It is a 1-800 number within Massachusetts, 1-800-377-9237.

The CHAIRMAN. Say it again. Just say it one more time.

Mr. MISILO. The number within Massachusetts is 1-800-377-9237. That's within Massachusetts, Monday through Friday, 8:30 to 4:30 p.m. And TDY number is 617-899-4861.

The CHAIRMAN. OK. Well, that's very helpful.

And I just will recognize Ms. Baldwin just concluding with you.

You know, you worked over that consent form earlier, you know, you heard from our two very moving witnesses earlier today. Even if that form were sent to some of these parents, you are going to have lots of children who don't have, effectively, active parents and you also wonder whether whatever happened with those individuals as well.

Dr. BALDWIN. Yes, I just wanted to clarify the record since we didn't discuss the funding of the study. There was some public health support for that study that was not entirely Quaker Oats.

The CHAIRMAN. OK.

I want to just go down the line here just of our witnesses and then I have one final witness I want to recognize Representative Markey. This addresses the point that I was concerned with earlier and that is whether you can give us, or maybe Dr. O'Toole can help us on that, whether there is any research being done on any human subjects now that are not in conforming to the protection of human subjects, rules and regulations.

Dr. O'TOOLE. We have no reason to believe that there is, Senator.

The CHAIRMAN. Maybe I could go down the list in terms of the Department of Defense.

Dr. SOPER. Speaking for the Department of Defense, we have in place a set of guidelines. This is a directive sent out by the two offices in the Department of Defense that will be actively involved in experimentation. The Defense Director of Research and Engineering and Health Affairs and we have guidelines, very strict guidelines, Department of Defense guidelines.

The CHAIRMAN. I'm not asking you whether you have guidelines. Do you have any information as a result of this over the period, say, since the 1974 rates went into effect, is there any human experimentation that is being supported by DOD or any of its agency?

Dr. SOPER. No, sir.

The CHAIRMAN. On human beings without complying?

Dr. SOPER. No, sir.

The CHAIRMAN. Dr. Albert?

Dr. ALBERT. I have no information to that effect and no reason to believe that it's being done.

Dr. BALDWIN. I would characterize the possibility of that as remote.

The CHAIRMAN. Just finally, Dr. Soper, I was listening with great interest when my friend Ed Markey was talking with our scientists about the Cold War mentality, whether this had impact and the effect of it. And you know when you look at the totality of this instance of what was happening in DOD, Dr. Soper, you stated in your written testimony that the Administration's Task Force on Human Radiation Experimentation will be run separately from the

nuclear test personnel review which tracks participants in the atmospheric nuclear testing between' 45 and' 62.

We addressed some of that in our Committee, the "Down-Winders" bill. We can only see that, you know, it was hardly scratching the surface on that.

Could you elaborate on the nature and the frequency of those testing experiments?

Dr. SOPER. The nuclear test personnel review is a program that was established in the late 1970s, I believe 1978, Senator, to review the incidences of health effects by those soldiers and others that participated during atmospheric test days. The program that we have, it's a national program. It's a model for what we hope in the DOD to use for following up these issues.

There are about 400,000, I think it's like 400,000 registrants to that nuclear test personnel review program where I think if I'm not mistaken we are following about 60 or 70,000 active cases today. It is a program that has reviewed the records, like we will do in this issue. It has established an outreach program and 800 number, and it is following up any inquiries from the public with information that they require.

The CHAIRMAN. Well, we will want to take another look at that and find out the lessons from that review board in terms of this experience.

Congressman Markey?

Mr. MARKEY. Dr. O'Toole, one of the principle answers I think that we have to have answered, again, goes back to whether or not my 1986 report is the iceberg or just the tip of the iceberg.

The Fernald School is in my Congressional district. Framingham VA is in my Congressional district. And yet those records were not given to me. And so it clearly raises the question if within my own Congressional district, then I was chairman of the committee back in 1986, whether two contracts that have already come to light here might be replicated many times over across the country. And that my report did not reflect in fact the iceberg at all.

Do you have at this time any preliminary sense of why this set of revelations might become, over the next several months, as these other agencies go through their records, including the Department of Energy, because after all, it was the Department of Energy that was responsible for at least giving me their records back in 1986.

Dr. O'TOOLE. Congressman, I don't.

When Secretary O'Leary responded to inquiries in the press about the plutonium injection experiments which were first revealed even before your committee put together and had been recently reviewed by the Albuquerque Tribune. We quickly realized that we did not know, in the Department of Energy, exactly how the experiments noted in your report were selected at the Department of Energy, or whether as you say they represented the bulk or all of the experiments that might be considered, or were a subset of that. And we've got to go back and figure that out, as we have endeavored, to cope with the document retrieval process.

We recognize that it is going to be quite a task to map all the different paths that one might follow in tracking down and capturing these now decade-old documents that might refer to these experiments. As I said, there is no easily accessible central index that

would tell us what experiments were done and where. Because we are now looking at experiments that might have been carried out sponsored government wide, we have a lot of terrain to cover and we expect to have to develop a very robust strategy to track down all the relevant documents.

Mr. MARKEY. So you have no comments that I received what I requested back in 1985 or 1986.

Dr. O'TOOLE. I do not know that you did, correct.

Mr. MARKEY. Dr. Soper, at the Department of Defense during the time period that we are referring to, the ' 40s through the early 1970s, what role did the Pentagon, especially the Defense Nuclear Agency, which has long been responsible for studying the effects of nuclear explosives, what role did it have in funding or requesting nuclear radiation experiments involving human subjects?

Dr. SOPER. Congressman Markey, part of our review is to determine, as I said, I in fact grew up my early part of my professional career was at the Defense Nuclear Agency. And the best of my knowledge, we did not fund any of the experiments using—radiation experiments using human subjects.

Part of the Defense Nuclear Agency was the Armed Forces Radiobiology Research Institute at which place experiments were conducted on primates and animals.

Mr. MARKEY. What about in other parts of the Defense Department? Can you speak also to whether or not they may have used or contracted out for experimentation upon human subjects?

Dr. SOPER. A good question and it's a part of the interagency process to try to uncover all information that would relate to this topic. I can tell you a little bit about the process through which we are going to do that. I can give you very little substance at this time. And we've just gotten started, we've gotten started well, I think.

Mr. MARKEY. Dr. O'Toole, during the last few weeks we have learned about this Fernald contract which really should have been given to my subcommittee back in 1986 as part of my inquiry.

Yesterday there were press reports regarding tests done out at Los Alamos which involved exposing up to 70 lab workers, their families and their children, to radiation. According to the press reports, subjects were exposed to tritium and radioactive hydrogen to determine how the body metabolizes radioactive substances.

Can you tell us what you know about those experiments and why children, one reportedly only 4 years old, was used in those experiments at that time?

Dr. O'TOOLE. Congressman, I can't tell you anything other than what I have read in the press. One of the aspects of the government effort to get at the information on these issues that we are going to have to deal with is the reality that cases and experiments are going to be surfaced by the press and by individual institutions, and indeed by individuals. And the government may not have the information first. And that's the situation I am in now.

As far as we can tell at the moment, there are at least four categories, four types of experiments to be considered. The first category are experiments designed to determine the health effects of radiation on the human body. That would include, for example, the plutonium injection experiments.

The second category are experiments in which radioisotopes were used to track normal metabolic processes in the human body, but where radiation itself was not the primary subject of concern.

The third category were experiments that were designed to try and develop new therapeutic modalities for radiation, in other words, to try to develop new medical benefits for the applications of radiation, and for example, treating cancer patients.

And a fourth category, which at this point is largely unexplored, were intentional releases of radiation to the environment to, for example, see if we can track the dispersion of radiation as might occur in warfare situations. But other than that, I can't speak very much in detail to particular experiments at this time.

Mr. MARKEY. Dr. Albert, Dr. Belton Burrows on the first panel says that he has 150 notebooks concerning experiments at the Framingham VA. As you know, that hospital is closed, as are many of the 53 facilities where testing took place.

Where are the records of all of these facilities, Dr. Albert?

Dr. ALBERT. I think there is a good chance that a lot of those records are just plain lost, Congressman.

Mr. MARKEY. So the fact that Dr. Burrows kept voluminous records of the Framingham VA, and took personal responsibility to do so, may just be a fluke?

Dr. ALBERT. Yes, that's right.

Mr. MARKEY. Is that correct?

Dr. ALBERT. That is correct.

Mr. MARKEY. So that you are saying that for the Framingham patients, there may be an ability to go back and recreate the records and to give some information to those patients.

Dr. ALBERT. That's right. Probably will be.

Mr. MARKEY. But to most of the rest of the people who are going to VA's across the country, that the VA's policy during that period of time may have resulted in the destruction of the records which will make it possible for us to let those families know what happened to their family member at a VA at that time?

Dr. ALBERT. I can't say if it's most, or what the percentage is. But I do think that it's likely that some of those records were indeed lost. You're correct about that.

Mr. MARKEY. Again, and let me again, it is not clear how many of these facilities were in fact involved in radiation testing initially. We heard it was 14, and then it went to 33, and now we hear that it may be 53 VA's across the country experimenting. Can you tell us now whether or not 53 constitutes the total universe of facilities that were being used?

Dr. ALBERT. I'm trying to get a hard fix on that.

Every time we go out with a request for information, we get a little more information.

And what Secretary Brown has done now is sent out a sweeping letter with a very specific list of questions which will allow us to answer that question in a quantitative fashion.

Mr. MARKEY. Can I just ask, do you have a policy in place right now? I know I am very impressed by Secretary Brown's attitude on this subject, but have you made it clear to everyone who may be out at these VA's right now, that they are not to destroy any records?

Dr. ALBERT. Oh, yes, that's quite clear.

Mr. MARKEY. All right. Fine. Because this is going to be very important.

Let me just finish up here by asking you, Dr. O'Toole, the DOE recently provided me with a copy of a 1951 Atomic Energy Commission Report entitled, Isotopes: A Five Year Summary of U.S. Distribution.

Now, this report summarizes the distribution of radioisotopes on the ADC and various researchers around the country, including the researchers out at the Fernald School.

Press reports indicate that the DOE is presently reviewing this report to identify other potentially problematic experiments that may have been conducted. I also understand that there may be subsequent editions of this publication in existence which may shed light on other disbursements of radioisotopes that may have been used in human experiments.

Can you confirm whether DOE is using this report to identify problematic experiments and whether you have found any later editions of the isotope reports?

Dr. O'TOOLE. We are definitely going to use that index as part of the strategy that we will pursue in examining experiments that the advisory body might review. I do not personally know of any other editions of that index. They may exist, Congressman.

Mr. MARKEY. Let me ask you as well, have you, have you notified all of the DOE contractors that they are not to destroy their records?

Dr. O'TOOLE. Yes, Secretary O'Leary has sent out a very clear message.

Mr. MARKEY. Has the Department of Defense done the same thing?

Dr. SOPER. Yes, I have Mr. Aspin's letter with me. Please advise all persons responsible for document disposal the need to preserve these records.

Mr. MARKEY. The same thing at the VA?

Dr. BALDWIN. It's going out today.

Mr. MARKEY. OK, thank you.

One final question, Dr. O'Toole. The 1951 agency report contains numerous references to the distribution of radioisotopes for confidential applications. For example, according to the report, shipments of cobalt 60 were sent to Tracer Lab, Inc., in Boston. The mixture of radioactive isotopes from uranium fission was sent to Ionics, Inc., in Cambridge. A shipment of cesium 137 was sent to MIT and shipments of cobalt 60 were sent to General Electric. In light of the concerns that have been raised about the use of radioisotopes and experiments involving human subjects, do you think it would be possible to declassify these records relating to all of the shipments for confidential applications so that the public can know for what purposes the isotopes were used?

Dr. O'TOOLE. Yes. Secretary O'Leary has already initiated a massive declassification effort in the Department of Energy. This is part of President Clinton's openness initiative, and the President has given very clear directions to this Task Force that all relevant materials be declassified as quickly as possible. And I expect that some of the shipments of isotopes that you enumerated, Congress-

man, were kept confidential for proprietary reasons, trying to develop industrial applications for radioisotopes. Whatever the reasons, we will find out, we will declassify as necessary, and we will make public absolutely everything that we have.

Mr. MARKEY. Well, Secretary O'Leary is my hero, and I just want to again congratulate her and her candor and congratulate as well Commissioner Campbell and Mr. Misilo for their work in dealing with this in a very forthright manner for the people in the State of Massachusetts.

The CHAIRMAN. Just finally, Ms. Baldwin, when I asked about whether any tests were taking place today on human subjects and I think you said the chances are remote.

That does not mean no, they are not. What does remote mean?

Dr. BALDWIN. Remote means that we have procedures in place that would——

The CHAIRMAN. You know of none.

Dr. BALDWIN. I know of none. I have no reason to believe that there are any.

The CHAIRMAN. And if you find out that there are some, will you let us know?

Dr. BALDWIN. Absolutely.

The CHAIRMAN. I would just like to ask Commissioner Campbell just to try, and some of our witnesses, as I understand just talking with the Commissioner, and he will tell us. You are going to review with those members of the science club? You're going to find out who those individuals are, and you are going to be in touch with them, as I understand it?

Mr. MISILO. That's right.

The CHAIRMAN. And as we know here in Fernald School, we have not only mentally retarded, but we also have behavioral challenges as well. The students who did at that particular time. And as I understand, many of these individuals who probably were here at the time probably are under Medicaid, I guess, am I correct?

Mr. MISILO. Yes.

The CHAIRMAN. You correct me or make response.

But that you do have good ability in tracking or finding out and determining in working with the MIT, who these individuals are? And I understand that they are going to track those individuals down. You are going to notify them, and you are going to help and assist them through the State health care system, through the Medicaid system, those that are eligible, and that you are going to let us know at the Federal level if there is some other kinds of problems that you are facing at the State. And that is going to be taking place, now, currently?

Mr. MISILO. Yes, it is.

The CHAIRMAN. And give us some idea in terms of time so people will have some idea?

You know, what is your best estimate?

Mr. MISILO. I would hope——

The CHAIRMAN. Are we talking weeks, months? What can you tell us?

Mr. MISILO. We are talking weeks. I think by the end of January, middle of February, I would anticipate we would have contacted everyone.

The CHAIRMAN. Now, will that be true with regard to the other institutions that we have here in the State that have been in any extent at all in any of these kinds of activities?

Mr. MISILO. Senator, I really couldn't comment on facilities beyond the Department.

The CHAIRMAN. But what you can tell us and what you can tell everyone in Massachusetts is that to the extent that you know, or we know, or we know at the national level, what has happened here in this State, you are going to notify these individuals and that they are going to be helped in some way in terms of medical help and attention? And as I understand from the Commissioner that this kind of information can be extremely helpful to those individuals in terms of maybe adding additional information in terms of helping their health care professionals treat these individuals or perhaps even their children.

Mr. MISILO. Yes.

The CHAIRMAN. In a medically appropriate way.

Mr. MISILO. Yes, particularly the testimony we've heard this morning regarding concern for the children of the patients, we certainly want to be able to reach out to them and provide that kind of information to the general practitioner, to the children's physicians certainly.

The CHAIRMAN. Maybe I will ask the Commissioner maybe if he can comment on this. Because I think it is important, for people here in our State to know that we have to deal with these policy issues, but witnesses today want to know what this is going to mean and when. We are going through these kinds of anxiety every single day.

We want to try and find out what we can do at the Federal level, what we can do at the State level, what we can do together.

Mr. Campbell. At the State level, we expect to review, not only review all of the records that we have connected with the Fernald State School, across the Commonwealth, in the last few decades, but there has been nine separate campuses upon which mental retardation and other disabilities have received services. Following the Boston Globe Sunday paper that brought this to our attention and others, I directed all the facility directors across the Commonwealth to search through all available records, the archives, and come forward to the Task Force that Deputy Commissioner Misilo is chairing with all such information that would lead us to believe that experimentation and research of questionable impact may have been conducted. The commitment of the Department is for full disclosure to each and every one of those individuals. We are committed upon being confident in the list, and I think that's important. This has led to a lot of apprehension and fear by people of what might have happened to them decades ago. So we want to be cautious to make sure that we are confident in the list that we finally conclude of people who may have participated both here on this campus and other campuses, that they did in fact participate. And the Department is committed to locating them, to determine whether or not there is any current impact upon them for the experiments, disclosing all information that we will uncover to them, for them to use for whatever purposes they have, and with respect to any medical needs that they have, work through the State

health care plans that are in place and any other plans that either are in place or may need to be in place.

If there are other cases where extraordinary medical needs become known to small segments of people who were either part of inoculations or experiments. And Senator Kennedy and I have just spoken about the possible need that the Federal and State governments will need to work together to provide additional health care above and beyond that which is normally available through Medicaid or private insurance programs for people.

And I think that the potential impact on additional generations, the sons and daughters of the men who were part of the Fernald science club or the men and woman who may have been participants across other campuses in Massachusetts, also deserve our attention and support. And the Department is committed to trying to assist them and their general practitioners with any necessary information which will help them better meet the health care needs of both the primary generation and following generations have.

The CHAIRMAN. Well, Commissioner, I thank you for that statement. I think we know that Dr. O'Toole is going to take time to assemble that material and collect all the information, but I would just suggest to Dr. O'Toole that to the extent that we can move early, as I hope Massachusetts, as our Commissioner and others have commented on, that will be the, you know, the national mood. I'd like to see Massachusetts lead the way.

And I want to tell you, Commissioner, I know we will work with you in every possible way to make sure that it is done, to the extent we can help at the Federal level, and I think we really commend you for those efforts.

Mr. MARKEY. If I could, I think we want to make it quite clear that we know that every employee of the Fernald School here is appalled as human beings could be about this. Most of them have dedicated their whole lives to helping children like those boys.

And it must upset them more than almost anyone else, those people that dedicated their lives to those boys. And I think we should note those people who have worked here all of those years and perhaps tens of thousands of families who entrusted their children to those workers. Because this must be a sad day for them, but I think we owe them the obligation of going through every record to let them know that this was the aberration, and that otherwise, people were treated with respect by their government and we thank especially our opening two witnesses because they were part of that. But I think there is many other people who are proud of you, too, what you have done with your lives as well.

The CHAIRMAN. I join Congressman Markey. We really appreciate it. I know he has, I have been here many different occasions, worked with the people, and we have had great interest to the problems of mental retardation, our families in particular, and if not personally, as well as professionally as a member of the Senate. So we have worked very closely with the people here. And I want to join with Ed. They do a remarkable job and we are grateful to all of them for the good work.

I want to thank all of our friends who have come up from the Administration. I hope they found that this was somewhat useful as well. We are all in this really together. And we want to work

closely with you and we are grateful to you, as well as your second row here. We see some good friends back there that can help make things happen. We thank all of you very much for a very constructive, helpful, positive, useful comments on a very difficult and painful and dark side of our medical past. We thank you very, very much.

And we will let this panel and go and move to our third panel, which I hope our guests will remain.

(Recess.)

The CHAIRMAN. If we could move ahead with the panel.

Our third panel will help us set these experiments into the ethical context of their day, were the investigators conforming to the prevailing ethical standards. Was there a general lapse of ethical standards among researchers for National Security concerns causing us to turn a blind eye. As a nation we are extremely interested in understanding whether the safeguards we have in place today will prevent similar studies from being performed: The question on everyone's tongue is could this happen today?

And our third panel is composed of Dr. Kenneth Ryan, the Kate Macy Ladd Distinguished Professor of Obstetrics and Gynecology, Harvard School of Medicine. Dr. Ryan was the former chairman of the National Commission of the Protection of Human Subjects of Biomedical and Behavioral Research.

He is joined in that panel by George Annas, Utley Professor and Chair of the Health Law Department, Boston University School of Medicine and Public Health.

Dr. Ryan has been a long time friend and one of—an individual that really has made an extraordinary difference in terms of research and ethics. As all of us in the Congress know, one of the extraordinary aspects of our protection of human subjects panel is that it never had any enforcement mechanism whatsoever. All it did is publish its recommendation in the Federal Register. And the power and the good sense of those regulations were accepted really without exception. And those individuals that served on that panel made an extraordinary public contribution and I think all of us who have seen what has happened are thankful that those kinds of matters are not happening today.

As I mentioned earlier, we are hopeful to hear your recommendations so that changes that ought to be made in terms of the future should be made. And I am enormously interested whether they think a follow-up kind of a panel could be of some use as we look into a wide range of different ethical choices and decisions we have to make.

We are legislators and we are generalists and we need the kind of thoughtful consideration which ethicists, theologians and members of all of the great churches and synagogues make on these matters and those consumers, lay people as well as medical people as well, we desperately need, as we move into a more complex world. And I think it has been illustrated in the last couple of weeks again in the newspapers across the country, we need a lot of help and we are fortunate to have two individuals who have been very helpful to the country in the past. We look forward to their testimony.

We will ask everyone if they will take their conversations. We do this nicely, but we do it. So we will ask for your cooperation, please. Take your conversations outside.

If you would please. Thank you very much.

STATEMENTS OF KENNETH RYAN, M.D., HARVARD SCHOOL OF MEDICINE; GEORGE ANNAS, M.D., CHAIR, HEALTH LAW DEPARTMENT, BOSTON UNIVERSITY SCHOOL OF MEDICINE AND PUBLIC HEALTH

Dr. RYAN. Senator Kennedy, I feel somewhat anticlimactic after the people that have testified before us. And I want to thank you for inviting us, you and Congressman Markey.

I think the way the story came to the American public is of interest. It's already been referred to. Congressman Markey had his report. It was 1986. Not much reaction. And then this Helen Welsome from the Albuquerque Tribune who 6 years had to fight with the Freedom of Information process to get enough information to release a story which was released in November of 1993. Still not too much reaction.

And it was only until Hazel O'Leary made her startling announcement and promised to make all the secret files public that we now see a public reaction. It took all of that to get the public properly informed.

So I think it's a lesson in the length of time that when one has these kinds of things under the rubric of secrecy, that we don't have protection. That was one point I wanted to make. The other was I wonder why people were reacting so violently to this, after the fact we had no regulations and theoretically this couldn't happen again and yet I understand——

The CHAIRMAN. Well, hold please. Could I ask those that are in the back of the hall, could I ask those in the back to take their conversations outside, please? We have a very important panel and we want to extend them the courtesies that we did the others. We are very grateful for the cooperation. But these individuals are entitled to be heard. So I would ask their cooperation, and thank you.

Dr. RYAN. What is the public uproar about? I think it's about the secrecy, what seemed to be the utter disregard for human safety. And the whole question of people at home, whether they need reparation. I think that is what is coming out of this. It is also a reminder to us that we have to inform new generations about our history. They are very easy to forget the things that we did he in the 1970s when we teach medical students about this now, we have to keep reminding them that we've done a lot in the past and they have to understand why we did it.

And finally I want to stress, and this is going to be one of my recommendations to you, is that protection oversight must be an ongoing process. When you go down the line and you ask anyone sitting here, is any research that shouldn't be going on, going on. And they say, I don't know. I don't think so. No, or something. They don't know.

And the only way they will know is if Congress puts in place a review process that they have had in the past in which site visits were made and the Institutional Review Boards were monitored to find out whether or not they were in fact complying. I think unless

you have that kind of compliance, that kind of review, no one will be totally assured that things are in the right.

I want to put the experiments in perspective. It's been brought up before. Some of the experiments were really horrific. Giving plutonium to people, injecting them. The other with the tracer doses. Both kinds of studies were wrong. I suspect when you asked for Atomic Energy requests, Congressman Markey, you wanted the plutonium data and they thought you probably weren't interested in the radioactive iron tracer studies or what have you. But both types of studies were wrong.

They were wrong because they were done in secret, many of them. They suffered from a lack of prior review, prior adequate review because at that time there were no Institutional Review Boards. And there was no national oversight in that regard. And there was a lack of adequate informed consent either from the subjects or from their parents or guardians. And that was a typical failing of research in those days, for the most part. That does not occur today.

It was customary to try to perform studies in institutions like Fernald for administrative convenience, rather than because the studies had relevance to the lives of the people that were here. The National Commission condemned that in 1978. We made a site visit here and we condemned the conduct of any kind of research in such institutions that didn't in fact mean something to the people, that would in fact improve their lives.

The Congress in 1974, the National Research Act that established our commission requested within a very large mandate that we make specific recommendations with respect to the protection of subjects who were—this is now in quotes from the Congressional request, institutionalized as mentally infirmed.

We did a report in 1978. We sent it to the Secretary of HEW, to the President, and to both houses of Congress. And to this day, this document has not been adopted. It's ironic that we should meet in this institution today. I understand that it was published in the Federal Register. It's the only thing that wasn't enacted. The response may not have been favorable. But rather than coming out and dealing with it, it's just been ignored. And I think, I think it's time. I request that you look at that.

The CHAIRMAN. I think we will get it adopted.

Dr. RYAN. As you know, we were followed by the President's commission. They had a charge to look at the conduct or research and it was that President's Commission from 1979 to 1983 that did site visits at Institutional Review Boards and actually made a recommendation that Congress continue oversight on the Federal agencies to make sure that they did comply with all of the recommendations on human subjects.

The President's Commission, and as you know, I personally have asked in the past that you consider recreating the ethics advisory board. That was supposed to advise the Secretary of HHS on the ethical conduct of research. This has not been done, as you know.

And I think that continued oversight of local Institutional Review Boards, including site visits, have to be, have to be brought back to the floor. So I want to close briefly by saying I'd like to take this opportunity to call for the creation of an ethics advisory board

within HHS to advise within HHS for the creation of a commission to follow in the pattern of either the National or the President's Commission to provide oversight of human subjects protection research sponsored by all Federal agencies.

And as you know, it must be very, very difficult for the CIA or the intelligence community to give us any assurances about any kind of research they are conducting, unless someone has oversight and can go in and see whether research subjects are being protected.

Very often when we ask Federal agencies about these things, this is in the 1970s, they said they weren't doing human subjects research. So it's only in this way I think that Congress and the public can be assured that we will have adequate protection of human subjects and at the same time we have to allow research to proceed, medical and scientific studies, to help people. And it's that fine balancing act which I think is necessary. That's why I think we still need the oversight. Thank you again.

The CHAIRMAN. Thank you very much, Dr. Ryan. You have been helpful, I know, in reviewing many of these ethical issues. We are appreciative of those efforts.

Dr. ANNAS. First I'd like to endorse the recommendation of Dr. Ryan. I'd actually push them a little further and to spend a couple of minutes summarizing for you my current thoughts on this issue and to put the experiments here in Fernald into perspective. I don't think I have to spend too much time on that. I didn't hear any witnesses really trying to justify the way they were done, and I think that's because you can't justify it, on the way they were done. The residents here were used because they were convenient. The fact that they may not have been physically harmed or were not harmed that bad is certainly no justification for using them simply because it was convenient. And they were certainly harmed in terms of dignity harm, harm to their humanity, and even under the standards at the time, the Nuremberg Code, spelled out by the US judges in 1947, it was not justified. They did not do therapeutic research on anyone without their informed consent. And if they couldn't give their own informed consent, you simply couldn't do the research. You had to do it on someone who was able to consent.

So the standards if anything today might permit that type of research with IRB approval, although I doubt IRB would actually approve it, the standards at that time would not have permitted it and I don't believe the standards at this time should permit it either.

What I would suggest is that current regulations actually cannot be counted on to prevent studies like the nutrition studies that were done here at the Fernald. I would again accept Dr. Ryan's recommendation that the National Commissions recommendations regarding regulations on the institutionalized mentally disabled be adopted. They are, as he pointed out, the only recommendations of that commission that have not been adopted and because they haven't been adopted, there are no special regulations for the institutionalized mentally disabled and this is perhaps the most vulnerable population that exists.

Review committees are new. IRB's are new. And they certainly have made life better. I have a lot less faith in IRB's, however,

than many people do. They are composed almost exclusively of researchers and researchers tend to think that research is good, of course, they wouldn't be doing it, and tend to approve each other's research.

I think that the IRB system should stay, but it should be a majority, not a research mostly representing people from the community, and as many as possible, people from the population that you are actually going to draw on to perform the research.

It should be remembered that the Atomic Energy Commission had its own internal review committee that approved the use of institutionalized mentally retarded patients for the studies that we were talking about today.

So review committees alone, obviously, cannot protect human subjects. And Dr. Ryan is of course absolutely right to say just because they are in place, even the best review committees themselves need oversight. They need to be visited. I would go one step further and say also those site visits should talk to the subjects of human research and see if they understand what's actually going on.

So number one, we need to enact those regs for the disabled institutionalized patients, and number two, we have the Federal agencies here saying that they all adopt it, a common standard for human experimentation. And that's true to an extent. They've all adopted the IRB system.

What none of them have adopted, except HHS, are the special regulations for children, pregnant woman, prisoners, and of course no one has adopted the use of institutional mentally disabled regs. And all Federal agencies should be asked to adopt those as well. There is no excuse for using vulnerable populations or for not protecting them.

In a place I'd go further than Dr. Ryan, I would require, I would recommend amending those regulations for children and the institutionalized mentally retarded to say that this population should never be used for any research that could be conducted on a population that can provide no informed consent. In other words, there should be a strong presumption that we should not use subjects for research who cannot provide their own consent.

Finally, I would say that the major change in research in this country over the last 50 years and certainly on a post Cold War-era has gone from using vulnerable populations as we've seen for National Security research or for Cold War research, to using the terminally ill patient for a different kind of a war: A war on cancer, a war on AIDS, a war on mortality. And at this time the most vulnerable population in the United States is actually the terminally ill patient.

That may strike a lot of people as strange to say that, but one study that I would use to illustrate this is one Congressman Markey referred to in his 1986 study. He has referred to it again today in his op. ed. piece in the Globe. But I haven't seen it referred to anyplace else.

I think it's worth briefly talking about the Mass. General study in which five terminally ill cancer patients with brain tumors were selectively injected with uranium to measure just that, the amount of uranium it took to produce damage on the human body. There

was no evidence of consent from any of the individuals, most of whom were comatose, or semicomatose, although it is notable that the only woman in the experiment, permission to perform an autopsy was refused by the family.

But perhaps most striking in that report is the conclusion of the researchers at the Massachusetts General Hospital that, quote, of the common laboratory animals, man appears to correspond most closely to the rat in regard to intravenous tolerance to uranium.

This was a classic Cold War experiment. One could argue whether the Fernald tracer studies were or were not. Even though the AEC was involved, they were nutrition studies. The Mass. General study was clearly a Cold War study done just to see body's tolerance to uranium. And there was a view that you can't hurt someone who is dying, you can't hurt someone who is terminally ill. And you certainly can't hurt, I think the researchers would argue, someone who is in a coma. Well, I think that's wrong. And I think that we have seen time and time again the AIDS research, the cancer research, this same rationale being put forward.

Frank Ingelfinger, the former editor of the New England Journal of Medicine said, The thumb screws of coercion are most relentlessly applied to the most used and useful of all experimental subjects, the patient with disease. But of course the fact that someone has a disease, is not sufficient justification to research on them. And even in fact they have consented, consent alone is not sufficient justification.

The Nuremberg Code, the regulations require us to look at both the rights and the welfare of individual subjects. We should never even ask someone to consent, unless we have a valid research and made every effort to see that the risks are outweighed by the benefits and that the harms of the subjects are minimized.

The fact that terminally ill patients will, as physicians tell me, consent to anything, is a problem. Not an advantage. It's not something we should take advantage of. You have heard testimony from the Administration, there is no problem with current research going on in NIH, but the President's Commission in asking the National Cancer Institute in 1981 to tell subjects of phase one cancer studies, which are not designed to help them, that the purpose of the study is not to help them. It's nontherapeutic, nonbeneficial. The Cancer Institute refused. They want to use the phrase, "potentially therapeutic", even though there is no evidence that phase one cancer research has ever helped anyone. That's not what it's for. This continues to this day.

There is a debate about it. One can clearly say it's clearly unethical but the point again is that I think we need systematic review by this National Commission or something of that sort to look again at all vulnerable populations, to revisit the children's regs, the institutionalized mentally disabled regs and to look at other vulnerable populations, especially the terminally ill patients, to see if there are steps that can be taken to protect them from exploitation. With that let me conclude those points. I'd be happy to try to answer any question.

The CHAIRMAN. Thank you very much.

Very helpful comments. Let me ask you, Dr. Ryan, are you aware of evidence demonstrating that the mentally disabled are still being used inappropriately as subjects?

Dr. RYAN. No, I'm not.

The CHAIRMAN. That means——

Dr. RYAN. But I'm not in a position that I should know. And I think my feeling about that is this is a large country. It is like asking you, are you on top of what's going on in Massachusetts.

The CHAIRMAN. Well, now, wait a minute. I'd like to be.

Dr. RYAN. But the answer to that question is I don't know. And I suspect that we don't get complete compliance in this regard, and I think you and I would like to know that we do.

I should point out, we've talked a lot about informed consent. And it is interesting that one of the giants in this field, Jay Katz, the lawyer from Yale has said, when he was young, he thought informed consent was really sufficient and would protect people. You not only need informed consent. You need peer review and oversight. So that in fact people are not asked to be involved in studies that may not be appropriate.

And the standards of the Commission was that we don't want people in institutions like Fernald to be forgotten here. We feel that they have problems that deserve care and consideration, but it's their problems. The reason why they are here or how to make their institutional lives better, that kind of research ought to be incurred. It ought to have relevance, however, to their lives and their importance and their families and the community ought to know what those research projects are and should approve them. That was the recommendation that we made.

We said that if the research is not relevant to them, it shouldn't be done in the institution, period. And I think had you had that kind of a policy going in the' 40s and' 50s, people wouldn't come to Fernald because it was convenient or as they did to other institutions.

The CHAIRMAN. Let me just ask you a rather particular question. And in the 1970s, we are looking at the establishment of the overall panel and the protection of human subjects. There was some sense that each of the agencies ought to have their own, and that that would be more, you know, more effective in trying to, just an example in the VA. I don't know if you have given that thought. I am going to introduce the legislation when we go back. I will just mention a word about it at the end of the hearing.

But do you have any sense whether we are better served by having the agencies establish their own or try to do an overall of really the distinguished and might get higher visibility and do the broad strokes and help you with some oversight.

Dr. RYAN. I don't think it's either/or. I think each agency has to have some sense of responsibility for what it is they are sponsoring. But, you know, we have asked prior Administrations to issue executive orders to make the HHS regulations apply to all Federal agencies and this was ignored. I guess it was accomplished in 1991 finally, by the new regs. It seems to me that for this kind of activity, you would need a national body that would look at all of them, rather than asking each Federal agency to try and in a sense watch themselves.

The CHAIRMAN. George Annas?

Dr. ANNAS. Absolutely, I concur with that, again when the representatives of the agencies say they don't know of any problems, that simply means they haven't looked. You know there are problems.

The CHAIRMAN. As you know, one of the real tragedies in the whole debate on choice was this panel. I mean, this is what happened after the President got elected. Even though the panel itself had not intruded on that enormously difficult and complex emotional issue, divisive issue which people have strong views, there are Constitutional issues involved. But that was the balance.

They were not going to continue to support that program, unless they had a majority of the panel that were committed in a certain way. And as a result, we never were able to get that panel to be put into effect and also to get the kind of support before it. I think hopefully we are beyond that, beyond the strong feelings and emotions on that issue. But hopefully we can fashion and shape a proposal that will help us.

Dr. RYAN. You are referring to the anguish that we have suffered in this country over the fetal issue. And it seems to me that there is enough work to do on the protection of human subjects that we can put that one behind us.

The CHAIRMAN. The tragedy was that fetal transplantation was taking place privately without any guidelines, without any protections, and all of the groups that were talking about, how can we have a panel in terms of the NIH which was going to have ethical standards established in terms of dealing with these issues. That wasn't good enough, and we continued along in the private sector doing fetal transplantation without any kind of guidelines, without any kind of oversight.

Dr. RYAN. I use the word moral vacuum. When the government withdrew and it got into the private sector and now I was reading where people have gotten AIDS from tissue transplantation, and we need very strict regulations on the use of tissue for transplantation.

The CHAIRMAN. But I think you are right.

Dr. RYAN. We want to do that separately.

The CHAIRMAN. I hear you.

Mr. MARKEY. Thank you, Senator. Let's just take a case study, the experiments that were conducted here at the Fernald in the 40s, the consent form that you've heard read here at the hearing, the responsibilities that you've heard from the various witnesses.

Do you think that that consent form was adequate at that time, using the standards of that time, what the scientists knew at that time?

Dr. RYAN. I don't want to be too pompous about this. A lot of people, you know, call it hindsight, if you will.

It seems to me, however, as George said, we already had the Nuremberg Code established. And I can tell you that researchers probably did not mention words like "radioactivity" so that the people would participate in the research, just as you implied. It was the standard of the time. It was not justifiable. I'm not sure everyone would have done research in that way.

Even the idea of who was supporting research, that it might have been for a commercial company and so on, we would require be disclosed to the individuals today.

So some people were trying to defend that because, you know, they are saying, well, we didn't know better in the 1950s. My response is we should have. And part of what we have gone through is that people of that era have retired and we have a different kind of young person coming up into medicine and into society. They have been through the' 60s and the 1970s with a different kind of attitude toward secrecy in government and they are asking for more disclosure, more honesty.

All I can say to you is that we can do good research being honest and being fair with people. That's the only way to do it. If you don't do it that way, it will in fact backfire. The answer to your question is I don't think it was right.

Mr. MARKEY. And Mr. Annas, the plutonium experiments that were conducted upon those who were considered to be terminally ill, I think is a very good point for discussion. The reality is that the patients were supposed to be terminally ill, were thought to be terminally ill. But several lived more than 20 years after they were injected with the plutonium. In fact, one of the terminally ill patients did not have stomach cancer at all but a very severe ulcer, and lived 23 years after he had been injected with the plutonium. That again forces the point which you were making about the difficulty in dealing with people who are thought to be terminally ill and their additional receptivity to these types of experiments.

Dr. ANNAS. There were so many cases where those kinds of comments were made about the life expectation, and they have been wrong. It was Paul Ramsey who I think published a lot on this question of whether or not one did research on terminally ill people just because they had no further interest and so on. And he said it was clearly ethically wrong. I'm sure you know Paul Ramsey, and now deceased who made a very, very strong point that people in those kinds of vulnerable situations should not be involved in that kind of a research. It's very hard to get informed consent under those circumstances.

The CHAIRMAN. Well, I want to thank our last panel. We are going to be in touch with them as we address legislation to deal with this issue. I will do everything I can to be sure that these recommendations are put into effect when we return to Washington. I'm very hopeful and expect that they would be. I am glad that you brought it to our attention. The other recommendations were so powerful and made so much sense.

I am encouraged by what our distinguished Commissioner Campbell and others have said about how they are going to come to grips with those that have been affected in our State and a strong, strong commitment that they have made to each of those individuals, and the properness with which they are going to address their concerns. I think that that is very important and ought to be reassuring to those individuals and to their families. And we are going to work with them to ensure that that kind of help and assistance is on its way. Because I think that that is incredibly important. It is the least that we can do. We have a very important, I think, moral responsibility to do so. And we are going to work very closely

in every possible way that we can. And I know that the State is committed to it. I understand that the President is committed to it. We certainly are. I'm going to work on that tirelessly, both in terms of medical attention and care and assistance, and also in those individuals as we will see this whole process announced by the Administration involved in terms of those who have been really disadvantaged in a way in terms of their own livelihoods, are going to be able to receive the fair compensation, people's whose lives have been completely disrupted.

And I have every intention of introducing legislation and have the follow-up legislation for the protection of human subjects and we will work very closely with our panelists here today and with others to make sure that we are going to be current in terms of the wide range of different activities that are taking place in the public resources, and also certainly in terms of the private research, as well.

And I think it is enormously important that we do. We will work with the Administration and we will work with all of those who have an interest. But I think we are reminded by this hearing that we have to be vigilant and tireless in our oversight. And in this issue we are really serious about it in terms of the future. This isn't just a single hearing. This is a continuing process.

And we are very, very grateful to all of those who have testified here today, who have commented. It has been very informative certainly to me. And we are going to move ahead with those observations and recommendations that have been made.

I finally just want to join all of those in really commending my good friend and colleague Congressman Markey who I think provided a number of very important and significant efforts in the public interest of his district, State, and country, and his service in this area is going to make an enormous difference in people's lives, in children's lives, family's lives, and those that have grown up now and have other families as well. It is enormous service for us, and I want to say how much all of us appreciate his leadership.

Mr. MARKEY. And I would like to say, if I could, that Senator Kennedy and his family have done more to take this whole subject of mental retardation since the dark ages of the' 40s and the' 50s to change the way that people view, people who are characterized that way, than any other single family in the United States. [Applause.]

And I think that most of the reforms in this country over the years reflect that. And I'd like to say as well again to Mr. Dyer and to Mr. LaRocque that their testimony was eloquent, and indeed the best question today that was asked was when Mr. LaRocque turned to Dr. Brill and asked simply, would you let your son participate in these experiments knowing what you know now.

I think that all of the teachers and personnel here at the Fernald School were very proud of both of you. And I think it has been a good day for this group to let people say what they could produce for good as well as this I hope aberration experiment.

The CHAIRMAN. I thank Congressman Markey. I will just take one moment as a chair and mention that my sister Eunice at the Eunice Kennedy Shriver center here, I am going to get a chance

to stop over there later on this afternoon and see how people are doing there.

I thank all of you for your kindness and for your patience. We hope that you've learned as much as all of us have and are motivated as we are. And the Committee stands in recess.

[Whereupon, at 2:30 p.m., the committee was adjourned.]

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